UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re: COPAXONE ANTITRUST LITIGATION	Master Docket. No. 22-1232(JXN)(JSA)
This Document Relates To: Third-Party Payor Class Action	

CONSOLIDATED CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

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Plaintiffs, the Mayor and City Council of Baltimore ("City of Baltimore"), Labor-Management Healthcare Fund ("LMHF"), and New York State Teamsters Council Health and Hospital Fund ("NYST") (collectively "Plaintiffs"), bring this action on behalf of themselves and all others similarly situated, against Defendants Teva Pharmaceuticals Industries Ltd. ("Teva Ltd."), Teva Pharmaceuticals USA, Inc. ("Teva USA"), Teva Neuroscience, Inc. ("Teva Neuro"), and Teva Sales & Marketing, Inc. ("Teva S&M") (collectively "Teva" or "Defendants"). These allegations are based on publicly available materials, investigation of counsel and knowledge, information, and belief.

I. INTRODUCTION

1. This case arises out of Teva's anticompetitive scheme to unlawfully thwart generic competition in the United States and its territories for its prescription drug Copaxone. The active ingredient in Copaxone is glatiramer acetate ("GA"), and it is an injectable medication approved for the treatment of patients with relapsing forms of multiple sclerosis ("MS"), including for the reduction of the frequency of relapses in relapsing-remitting MS ("RRMS"). Copaxone is Teva's best-selling product, generating more than $30 billion in revenue in the United States, including $3.5 billion in 2016 alone.

2. Since Teva began selling Copaxone in 1997, it has been able to raise the price uninhibited for decades. The annual cost of Copaxone has skyrocketed from less than $10,000 for a yearly course in 1997 to nearly $70,000 per year in 2020.

3. Following a multi-pronged strategy to delay generic competition, including through litigation and shifting the market from its 20 mg product to a 40 mg product, Teva continued its scheme both before and after Mylan Pharmaceuticals and Sandoz introduced a less expensive generic version of Copaxone 40 mg by employing multiple tactics to prevent the uptake of generic versions of Copaxone.

4. As one part of its scheme to foreclose uptake of generic Copaxone, Teva entered into multi-pronged "House Brand" agreements with intermediaries, including by entering into exclusionary contracts with Pharmacy Benefit Managers ("PBMs") and PBM-owned specialty pharmacies, in order to coerce them into blocking generics by (i) refusing to pay any rebates to the PBMs unless generic Copaxone was excluded from formularies, and (ii) reaching agreements with PBM-owned specialty pharmacies to dispense branded Copaxone even if a prescription was written specifically for generic Copaxone. By engaging in this conduct, Teva effectively prevented purchasers such as Plaintiffs and other class members from having any choice with respect to the product they purchased. Teva's conduct also denied its competitors the opportunity to compete. Lack of formulary coverage combined with the fact that specialty pharmacies were prevented from dispensing generic Copaxone resulted in the lack of generic uptake and substantial market foreclosure.

5. At the same time, as another part of its anticompetitive scheme, Teva engaged in a misinformation campaign, widely spreading false and misleading statements to convince prescribers and patients that generic Copaxone was less effective than brand Copaxone and/or that generic Copaxone manufacturers did not offer co-pay assistance, training and nursing support services and that generic Copaxone was a biologic or biosimilar or otherwise significantly different from brand Copaxone. Generic competitors could not correct this information because it was funneled through patient portals and nursing portals, and some healthcare providers refused to speak to the generic manufacturers. These false marketing statements convinced a substantial percentage of healthcare providers to write "DAW" prescriptions, circumventing automatic substitution laws and ensuring that they would be filled only with branded Copaxone even though less expensive generic alternatives were available.

6. Teva also duped health plans with an anticompetitive consumer copay "coupon" scheme that circumvented plan members' cost-sharing obligations and helped artificially increase and protect brand Copaxone's high prices.

7. Absent the Defendants' unlawful conduct, generic manufacturers of Copaxone would have been able to fairly compete with Teva in a full and timely manner, and Plaintiffs and Class members, who are "third-party payors" such as health insurers and self-funded health plans, would have substituted lower-priced generic Copaxone for nearly all of their Copaxone purchases and paid lower prices for their branded Copaxone purchases sooner. Plaintiffs and Class members would have purchased lower-priced Copaxone in substantially larger quantities. Instead, the Defendants' unlawful conduct allowed Teva to reap substantial amounts in ill-gotten gains and prevented uptake of the 40mg generic GA versions which has cost Plaintiffs and Class members hundreds of millions of dollars in overcharge damages. Plaintiffs and the proposed class seek to recover damages, including treble damages, under the state antitrust and consumer protection laws enumerated below and declaratory and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

II. JURISDICTION AND VENUE

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds $5,000,000, exclusive of interest and costs, there are more than one hundred members of the class, and at least one member of the putative class is a citizen of a state different from that of one of the Defendants.

9. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1332(d), and 1337(a).

10. This Court has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367(a).

11. The Court also has jurisdiction over this action pursuant to § 2 of the Sherman Act and §§ 4 and 16 of the Clayton Act.

12. The Defendants transact business within this District and/or have agents in and/or can be found in this District.

13. Venue is appropriate within this District under 28 U.S.C. § 1391.

14. Venue is also appropriate within this District under § 12 of the Clayton Act.[1]

15. This Court has *in personam* jurisdiction over Defendants because they, either directly or through the ownership and/or control of their subsidiaries, *inter alia*: (a) transacted business throughout the United States, including in this district; (b) had and maintained substantial aggregate contracts with the United States as a whole, including in this district; and/or (c) were engaged in an illegal scheme that was directed at, and had a direct, substantial, reasonably foreseeable, and intended effect of causing injury to the business or property of persons and entities residing in, located in, or doing business throughout the United States, including in this district. Defendants also conduct business throughout the United States, including in this district, and have purposefully availed themselves of the laws of the United States.

16. The scheme has been directed at, and has had the intended effect of causing injury to individuals, including Plaintiffs and Class members and companies residing in or doing business throughout the United States, including in this District.

[1] 15 U.S.C. § 22.

III. THE PARTIES

17. Plaintiff, the Mayor and City Council of Baltimore, is a municipality located in Baltimore, Maryland. During the Class Period, as defined below, the City of Baltimore purchased, paid, and/or provided reimbursement for some or all of the purchase price of Copaxone and its AP-rated generic equivalent for personal and/or household use from pharmacies located in and/or on behalf of members located in at least the following states: Delaware, Florida, Illinois, Kansas, Maryland, New Jersey and Pennsylvania.

18. Plaintiff Labor-Management Healthcare Fund is a self-insured health plan with a principal place of business at 3786 Broadway Street, Cheektowaga, New York 14227. During the Class Period, as defined below, LMHF purchased, paid, and/or provided reimbursement for some or all of the purchase price of Copaxone and its AP-rated generic equivalent for personal and/or household use from pharmacies located in and/or on behalf of members located in at least New York.

19. Plaintiff New York Teamsters Council Health and Hospital Fund is a self-insured health plan with a principal place of business of Syracuse, New York. During the Class Period, as defined below, NYST purchased, paid, and/or provided reimbursement for some or all of the purchase price of Copaxone and its AP-rated generic equivalent for personal and/or household use from pharmacies located in and/or on behalf of members located in at least New York.

20. Defendant Teva Pharmaceuticals Industries Ltd. ("Teva Ltd.") is an Israeli corporation with a principal place of business at 5 Basel St., Petach Tikva, Israel 4951033. Teva Ltd. owns subsidiaries, including Teva Pharmaceuticals USA, Inc., Teva Neuroscience, Inc. and Teva Sales & Marketing, Inc., which do business in the United States. Teva Ltd. has promoted itself as the largest seller of generic drugs in the United States with billions of dollars in revenue. But for Teva Ltd.'s subsidiaries, Teva USA, Teva Neuro and Teva S&M, Teva Ltd. itself would

need to act directly in order to achieve its goals marketing pharmaceuticals in this District and all other states.

21. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054. Teva USA is a subsidiary of Teva Ltd.

22. Defendant Teva Neuroscience, Inc. ("Teva Neuro") is a Delaware corporation with a principal place of business at 11100 Nall Ave., Overland Park, Kansas, 66211. Teva Neuro is a subsidiary of Teva Ltd.

23. Defendant Teva Sales & Marketing, Inc. ("Teva S&M") is a Delaware corporation with a principal place of business at 11100 Nall Ave., Overland Park, Kansas, 66211. Teva S&M is a subsidiary of Teva Ltd.

24. The Defendants' wrongful actions described in this complaint are part of and were taken in furtherance of the illegal monopolization scheme and restraint of trade alleged herein. These actions were authorized, ordered, and/or undertaken by the Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the Defendants' affairs within the course and scope of their duties and employment and with their actual, apparent, or ostensible authority.

IV. INDUSTRY BACKGROUND

A. The Hatch-Waxman Amendments provide for the approval of generic drugs that are bioequivalent to, and thus perfect therapeutic substitutes for, their brand drug counterparts.

25. Under the Food, Drug, and Cosmetics Act ("FDCA"), drug companies that wish to sell a new drug product must file a New Drug Application ("NDA") with the FDA. An NDA submission must include specific data concerning the safety and effectiveness of the drug, including information from at least two clinical trials.

26. An NDA applicant must also submit to the FDA information about each patent that purportedly covers the drug product, including methods of using the drug product, described in the NDA and for which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."[2] The FDA then publishes this information in a digest titled *Approved Drug Products with Therapeutic Equivalence Ratings*, known as the Orange Book.

27. The Hatch-Waxman Amendments, enacted in 1984, simplified regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.[3] A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA and must show that the generic contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and that it is bioequivalent, *i.e.*, absorbed at the same rate and to the same extent as the brand.

28. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic would be present

[2] 21 U.S.C. § 355(b)(1), (c)(2).

[3] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

in the blood of a patient to the same extent and for the same amount of time as the brand counterpart.[4]

29. Accordingly, when the FDA approves the sale of a generic drug under the Hatch-Waxman Amendments, it assigns that drug a therapeutic equivalence code. Drug products that the FDA considers therapeutically equivalent to the reference drug product are assigned an "A" code. Injectable drugs that have been determined by the FDA to be therapeutically equivalent to the reference listed product are designated "AP-rated." An AP-rated drug is therefore a perfect generic substitute for, its brand drug counterpart.[5]

B. The BPCIA provides for the approval of biological products which are biosimilar to, but not substitutes for, their reference biological product.

30. Under the Public Health Service Act (PHSA), as amended by the Biologics Price Competition and Innovation Act of 2009 (BPCIA)[6], the FDA also regulates biological products, also known as "biologics."

31. In some ways the regulatory process for biologics is similar to that for pharmaceutical drugs. Under the BPCIA, a biologic manufacturer may seek approval for sale of their product by demonstrating biosimilarity or interchangeability with an already-approved biologic.

[4] 21 U.S.C. § 355(j)(8)(B).

[5] The therapeutic equivalence code for an A-rated drug includes a second letter which generally provides information about the dosage form of the drug. For example, here Mylan's GA products are "AP-rated" which means they are A-rated drugs (A-) in the form of "aqueous injectable solutions" (-P).

[6] 42 U.S.C. § 262(k)(2).

32. However, biological products are distinct from pharmaceutical drugs regulated under the FDCA and Hatch-Waxman Amendments, and biosimilarity is distinct from bioequivalence.

33. An A-rated generic drug is bioequivalent to, and thus can be substituted for, its brand drug reference. Indeed, as described above, some states require pharmacists to substitute A-rated generics in for their brand drug counterparts. By contrast, although one biologic may be approved because it is biosimilar to another reference product, biosimilars cannot generally be automatically substituted at the pharmacy for their reference product "without the intervention of the health care provider who prescribed the reference product."[7] This is because biologics "are derived from living cells, biologics can never be exactly reproduced or copied like [traditional] generics," biosimilars must undergo a more rigorous and expensive process than generic drugs to receive FDA approval. A biosimilar manufacturer must show that its product is "highly similar" to the reference product and that there are no "clinically meaningful differences" between the two in terms of "safety, purity, and potency."

34. Biosimilars can only be substituted for their reference product without the intervention of the health provider if, after additional testing, the FDA also determines that they are "interchangeable." However, although it has been over a decade since the BPCIA was enacted, only two biosimilars have been determined to be interchangeable with their reference biologic.

C. Congress relies on generic drugs to reduce healthcare expenses.

35. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses

[7] 42. U.S.C. § 262(i)(3).

nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

36. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historically high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenues for brands and generics totaled $21.6 billion; by 2013, total prescription drug revenues had climbed to more than $329.2 billion, with generics accounting for 86% of prescriptions. Generics are dispensed about 95% of the time when a generic form is available.

37. Because generic versions of branded drugs contain the same active ingredients and are determined by the FDA to be just as safe and effective as their branded counterparts, the only material differences between generic drugs and their branded counterparts are their prices and manufacturers. Because generic versions of branded products are commodities that cannot be differentiated, the primary basis for generic competition is price.

38. Every state either requires or permits a prescription written for the brand to be filled with an A-rated generic. As a result, the first generic manufacturer almost always captures a large share of sales from the band.

39. At the same time, there is a reduction in the average price page for the drug at issue. Typically, generics are at least 25% less expensive than their branded counterparts when there is a single generic competitor. They are 50% to 80% (or more) less expensive when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a bioequivalent generic drug usually results in significant cost savings to all drug purchasers.

40. Once a generic comes to market, it quickly captures sales of the corresponding brand drug, often 80% or more of the market, within the first six months after entry. In one study, the FTC found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and (with multiple generics on the market) prices had dropped 85%. As a result, competition from generics is viewed by brand manufacturers as a grave threat to their bottom lines.

41. Until the generic version of a brand drug enters the market, there is no bioequivalent generic to substitute for, and thus compete with, the branded drug, so the brand drug manufacturer can continue to profitably charge supra-competitive prices. As a result, brand drug manufacturers, well aware of the rapid erosion of branded drug sales by generic drugs, have a strong incentive to delay the start of generic drug competition into the market. And once a generic drug enters the market, brand drug manufacturers have strong incentives to prevent their adoption. Both delay of generic entry and prevention of uptake of generic versions are achievable by brand drug manufacturers willing to engage in illegal conduct to exploit the unique structure of the pharmaceutical marketplace.

D. Brand drug manufacturers can delay potential generic competitors through litigation.

42. Under the Hatch-Waxman Amendments, if patents submitted with the brand drug manufacturer's original NDA and listed in the Orange Book have not yet expired, a generic manufacturer may certify as part of their ANDA that those patents are invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.[8] This certification is commonly known as a Paragraph IV or "P.IV" certification.

[8] 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A).

43. If a generic manufacturer files an ANDA containing a P.IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement.

44. If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of a P.IV certification, the FDA generally will not grant final approval on that ANDA until the earlier of (i) the passage of 30 months, or (ii) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA.[9] This period is commonly referred to as the "30-month stay."

45. Until the court issues a decision finding the patent invalid or not infringed or until 30 months has passed, the FDA may grant "tentative approval" to the ANDA filer, recognizing that the ANDA is approvable, but cannot grant final approval, which would allow the generic manufacturer to market its product.

E. Brand drug manufacturers can misuse citizens petitions to delay FDA approval of generic drugs.

46. Section 505(j) of the Food, Drug and Cosmetic Act creates a mechanism by which a person may file a petition with the FDA requesting, among other things, that the agency take, or refrain from taking any form of administrative action. This mechanism is commonly referred to as a "citizen petition."

47. Citizens petitions provide a forum for individuals to express and support their genuine concerns about safety, scientific, or legal issues regarding a product any time before, or after, its market entry. Other than the form it should take, the regulations place no restrictions on

[9] 21 U.S.C. § 355(j)(5)(B)(iii).

the subject matter of a citizen petition. A citizen petition may be filed to request that the FDA take action regarding drug approval requirements, including those involving generic drugs.

48. The FDA regulations concerning citizen petitions require the FDA Commissioner to respond to each citizen petition within 180 days of receipt. That response may be to approve the request in whole or in part or deny the request. The Commissioner also may provide a tentative response with an estimate on a time for a full response.

49. Reviewing and responding to citizen petitions is a resource-intensive and time-consuming task because, no matter how baseless a petition may be, the FDA must research the petition's subject, examine scientific, medical, legal, and sometimes economic issues, and coordinate internal agency review and clearance of the petition response. These activities strain the FDA's limited resources, and lengthy citizen petitions can delay the FDA approval of generic products even if those petitions ultimately are found to lack any reasonable evidentiary, regulatory, statutory, or scientific basis.

50. It is the practice of the FDA, well known in the pharmaceutical industry, to withhold ANDA approval until after its consideration of and response to a citizen petition is complete.

51. Abusive and anticompetitive citizen petitions have become an increasingly common problem in the last several years as brand name companies submit citizen petitions with respect to ANDAs with the purpose of delaying the approval of the generic product while the FDA evaluates the citizen petition.

52. The FDA has at times spoken out against these practices. Former FDA Chief Counsel Sheldon Bradshaw noted that in his time at the agency he had "seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality or

scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."

53. The FDA noted in a 2020 report to Congress that "the Agency continues to be concerned that section 505(q) does not discourage the submission of petitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues."[10]

F. Brand drug manufacturers can prevent pharmacies from automatically substituting generic drugs for their brand counterparts.

54. The marketplace for the sale of prescription pharmaceutical products in the United States is unique. In most industries, the person who pays for a product is also the person who chooses the product. When the same person has both the payment obligation and the choice of products, the price of the product plays a predominant role in the choice of products. Consequently, manufacturers have a strong incentive to lower the price of their products to maintain profitability.

55. The pharmaceutical marketplace, in contrast, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing certain drugs to patients unless they can present a prescription written by their physician. This prohibition introduces an anomaly into the pharmaceutical marketplace between the payment obligation and the product selection. The patient (and in most cases his or her insurer)

[10]FDA,*Twelfth Annual Reporton Delaysin Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2019* (2020), available at www.fda.gov/media/143518/download (last accessed April 29, 2022).

has the obligation to pay for the pharmaceutical product, but his or her doctor chooses which product the patient will buy.

56. In 1984, Congress sought to ameliorate the "disconnect" by authorizing the manufacture and sale of generic pharmaceuticals under the Hatch-Waxman Amendments. Since the passage of the Hatch-Waxman Amendments, every state has adopted drug "automatic substitution" laws that either require or permit pharmacies to substitute A-rated generic equivalents for brand prescriptions.[11] In this way, price reenters the product selection decision at the pharmacy counter, lessening the pharmaceutical marketplace "disconnect."

57. Brand drug manufacturers can evade these automatic substitution laws in several ways. First, brand manufacturers can engage in litigation or FDA petitioning tactics to slow or prevent generic approval.

58. Second, brand drug manufacturers can prevent automatic substitutions by instead marketing slightly different versions of their drugs for which there are not yet any A-rated generics; pharmacists cannot choose to substitute generics of the previous version.

59. Third, most automatic substitution laws also include a "dispense as written" or "DAW" exception that allows physicians to explicitly prohibit pharmacies from substituting AP-rated generic drugs for their brand drug equivalents.[12] By leveraging their dominant incumbent position and encouraging doctors to use DAW scripts to prescribe only brand drugs, a brand drug manufacturer can thus remove the pharmacist's ability to substitute generic drugs for their brand drug counterparts, remove price from product selection, and preserve the marketplace "disconnect" that enables the brand drug manufacturer's supracompetitive pricing.

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[11] *See, e.g.*, N.J. Stat. Ann. § 24:6E-7.

[12] *See id.*

60. Fourth, brand manufacturers may engage in anticompetitive contracting strategies meant to manipulate drug coverage or placement on formularies (i.e., the lists of "covered" drugs maintained by Pharmacy Benefit Managers ("PBMs") and third-party payors), placement that would otherwise encourage the use of cheaper generic versions of the drug and insulate the brand drug from generic competition.

G. Brand drug manufacturers can limit access to generic drugs by excluding them from insurance coverage formularies.

61. A PBM is an intermediary in the pharmaceutical supply chain that manages prescription drug benefits on behalf of their third-party payor health plan clients.

62. As their name implies, PBMs sell pharmacy benefit management services to their clients—typically entities like health insurance companies, self-funded health plans, and the government. Theoretically, PBMs leverage the collective purchasing power of those clients to extract lower drug prices from drug manufacturers and lower distribution costs from pharmacies.

63. PBMs manage pharmacy benefits by developing lists of covered prescription drugs, also known as formularies, on behalf of health insurers. Because these lists determine which drugs are covered by insurance plans, formulary placement largely determines which drugs covered individuals have access to. If a drug is not on the formulary, the health plan generally will not cover it, and the patient who is prescribed that drug must pay the entire cost out-of-pocket.

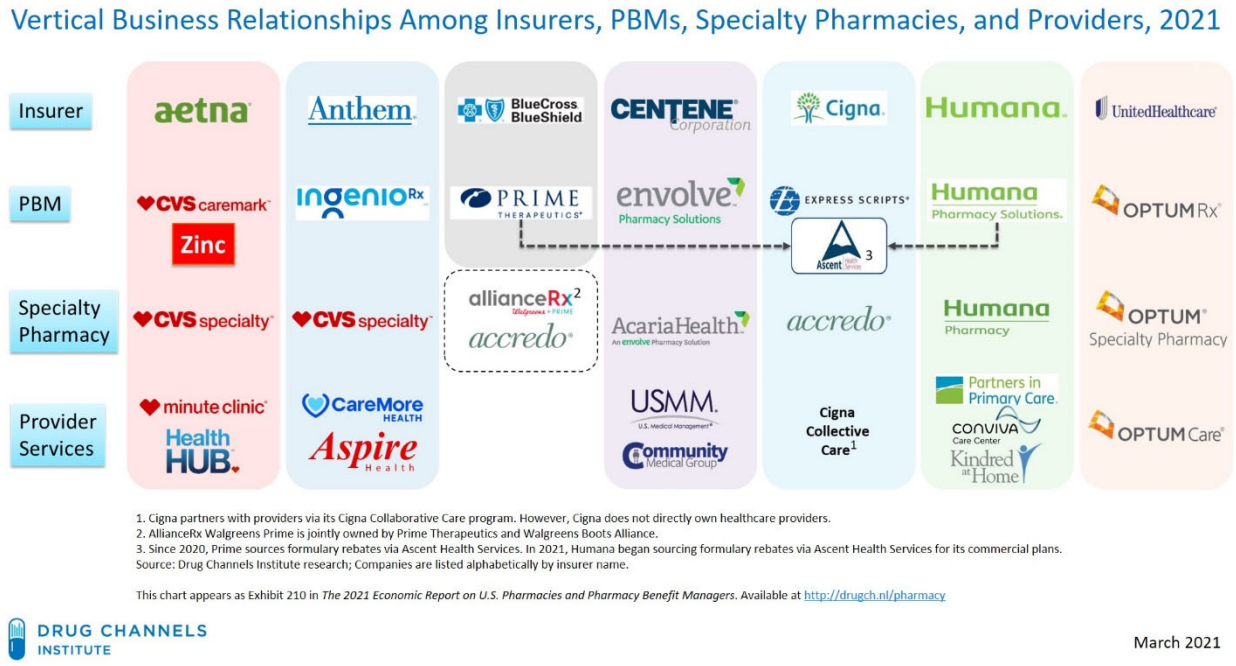
64. PBMs do not themselves buy prescription drugs from drug manufacturers. Instead, they negotiate "rebates" from drug manufacturers who want their products included on the PBM's formulary. Put another way, drug manufacturers pay PBMs to include their products on the formulary. PBMs then provide a portion of these rebates to their clients and give drug manufacturers access to their clients' covered members.

65. Similarly, PBMs do not themselves sell prescription drugs to pharmacies. Instead, pharmacies buy their drugs from wholesalers, then turn to the PBM's client for reimbursement after providing those drugs to an individual covered by the PBM's client—the health plan.

66. While drug manufacturers pay PBMs rebates to include their products on formularies, some manufacturers have begun to enter into exclusionary arrangements whereby they coercively condition those rebates on the PBM *excluding* competing drugs from the formulary or offering more favorable placement to the brand over the competing generic version.

67. The PBM market is extremely concentrated. The three largest PBMs—OptumRx, CVS Caremark, and Express Scripts—control almost 80% of the market for PBM services. This level of concentration means that by paying only a few different PBMs for formulary exclusivity, a drug manufacturer with monopoly power can foreclose a generic competitor from huge swaths of the market.

68. Moreover, certain PBMs own or are affiliated with specialty pharmacies and require plan members to fill their specialty prescription needs at that particular pharmacy. As illustrated below, five of the six largest PBMs, including the three largest, are vertically integrated with other health services providers, including specialty pharmacies. So, as an example, upon information and belief, members of Express Scripts' plans are required to purchase their specialty pharmacy drugs, including Copaxone, from Accredo, which is a wholly-owned subsidiary of Express Scripts.



V. BACKGROUND FACTS

69. The factual allegations that are set forth in this section are integral to demonstrating the lengths that Teva was willing to go through to thwart and suppress generic entry and provides context for the conduct that gives rise to Plaintiffs' allegation that Teva engaged in an unlawful scheme to suppress generic competition and thereby drive up sales of the brand and keep Copaxone prices high.

A. Copaxone is a Blockbuster Drug for Teva.

70. On December 20, 1996, FDA approved Teva's NDA No. 20-622 for glatiramer acetate therapy – 20mg/mL ("20mg") daily – an injectable drug to treat patients with relapsing forms of multiple sclerosis ("MS"), including relapsing remitting MS ("RRMS"). Copaxone is a medication for MS which helps reduce relapses; it does not cure MS. Therefore, patients typically take Copaxone for many years. Teva began marketing 20mg Copaxone in March 1997.

71. Given its characteristics as a specialty injectable drug, Copaxone is commonly dispensed through specialty pharmacies.

72. Teva's market exclusivity for Copaxone 20mg ended in May 2014.[13]

73. Copaxone is a blockbuster drug for Teva, yielding billions in annual U.S. sales, and representing as much as 21% of Teva's global revenue (and half of its profit) in 2014[14] and 19% of Teva's global revenue in 2017.

74. Teva's Form 10-K for the end of fiscal year December 31, 2017 identified Copaxone as its "most significant single contributor to revenues and profits."[15] As a result, Teva has had a significant incentive to delay and thwart the uptake of generic GA, given that such entry would, absent Teva's unlawful conduct, eviscerate brand sales and, correspondingly, its revenue.

75. Fearing the loss of Copaxone 20mg exclusivity and the concomitant dramatic drop in revenue that would result from generic competition, Teva turned to a series of strategies to prolong its monopoly on Copaxone before its 20mg formulation patents expired.

B. Teva Employed an Entire Playbook of Anticompetitive Tactics to Thwart Generic Competition for Copaxone.

76. Notwithstanding that Teva is the world's largest manufacturer of generic drugs, in this case, it manufactures a brand product and called upon all of its experience on the generic side of the market to derail other generic manufacturers' efforts to enter the glatiramer acetate market. Teva engineered a product "hop" from one non-patent covered product to another patent-covered product to move patients from the drug that was vulnerable to generic competition to the drug that had additional patent protection, thus decimating the prescription base for competing Copaxone

[13] The patents covering Copaxone 20mg were U.S. Patents Nos. 5,981,589; 6,054,430; 6,342,476; 6,362,161; 6,620,847; 6,939,539; and 7,199,098, all of which are listed in the Orange Book for Copaxone® 20mg and two process patents, 5,800,808 and 6,048,898.

[14] Andrew Pollack, *Generic Version of Copaxone, Multiple Sclerosis Drug, Is Approved*, The New York Times (April 16, 2015), https://www.nytimes.com/2015/04/17/business/generic-version-of-copaxone-multiple-sclerosis-drug-is-approved.html.

[15] https://www.sec.gov/Archives/edgar/data/818686/000119312518039076/d529462d10k.htm.

generics. Teva also filed serial citizen petitions with FDA to delay FDA review of generic GA ANDAs and lodged multiple infringement lawsuits against ANDA filers for generic glatiramer acetate formulations. In addition, following the period of exclusivity afforded by its patents, which ended in May 2014, Teva engaged in baseless patent litigation in order to further delay generic entry. Further, Teva implemented an anticompetitive copay couponing program and an illegal kickback scheme, both of which further allowed it to maintain its inflated prices for Copaxone and suppress uptake of generic GA.

77. Before *and after* Sandoz launched a generic 20mg formulation in 2015 and Mylan launched generic 20mg and 40mg formulations in 2017, Teva aggressively sought to foreclose all avenues of generic competition to Teva's Copaxone and to perpetuate its monopoly through anticompetitive means. Teva ran a behind-the-scenes campaign designed to manipulate doctors, PBMs, and patients to continue purchasing its more expensive Copaxone. As one district court observed in 2020, from the time that Teva first obtained FDA's approval to market Copaxone in the United States in 1996, "Teva has pursued every available avenue to prevent other glatiramer acetate products from coming to market."[16]

78. Simply stated, the long history of Teva's drug Copaxone is punctuated with attempt after attempt by Teva to snuff out generic competition. Teva's illicit acts have caused, and continue to cause, purchasers to pay higher prices and have barred some purchasers from obtaining generic versions of glatiramer acetate entirely. In order to stifle and block the onset of generic competition and continue reaping hundreds of millions of dollars annually from its Copaxone sales, Teva embarked on a multifaceted scheme to foreclose or severely dilute generic entry. One analyst put

[16] *Teva Pharm. USA, Inc. v. FDA*, Civil Action No. 20-808 (BAH), 2020 U.S. Dist. LEXIS 245082, at *23 (D.D.C. Dec. 31, 2020).

it succinctly: "It's not just that Teva doesn't want the FDA to approve generics of its MS star, Copaxone. It really, really, really does not want the FDA to approve them."[17]

1. Teva Raises Prices Aggressively.

79. Since first marketing Copaxone in 1997, Teva has increased the price of the drug at least *27 times*. In 1997, Copaxone was priced at $10,000 for an annual course of treatment. In 2020, an annual course of treatment cost nearly $70,000.

80. In fact, a September 2020 report by the Committee on Oversight and Reform of the United States House of Representatives ("House Report"), titled "Drug Pricing Investigation: Teva-Copaxone," found that "[e]ven Teva's own employees could not afford Copaxone at its price."[18] The exchange was captured in a Teva document, in which the employee lamented that she could no longer afford Copaxone, which would cost her $1,673.33 out of pocket, while Mylan's generic GA would only cost her $12 out of pocket.

81. The prices Teva charges for Copaxone in the United States is far higher than the prices it charges for the same product in other countries. For example, in 2015, the net price of Copaxone 40mg/ml was $126 per day in the United States. In sharp contrast, the exact same dosage was only $33 in Germany, $26 in Spain, $25 in the United Kingdom, and $18 in Russia.

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[17] Carly Hefland, *Teva takes another swing at generic Copaxone with new FDA petition*, FiercePharma (Apr. 2, 2015), https://www.fiercepharma.com/sales-and-marketing/teva-takes-another-swing-at-generic-copaxone-new-fda-petition.

[18] COMMITTEE ON OVERSIGHT AND REFORM, U.S. HOUSE OF REPRESENTATIVES, DRUG PRICING INVESTIGATION: TEVA-COPAXONE, (2020), https://oversight.house.gov/sites/democrats.oversight.house. gov/files /Teva% 20Staff%20Report %2009-30-2020.pdf ("House Report"), and the accompanying document packet ("House Teva Report Document Packet") is available at COMMITTEE ON OVERSIGHT AND REFORM, U.S. HOUSE OF REPRESENTATIVES, DRUG PRICING INVESTIGATION: TEVA-COPAXONE, (2020),

https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Document%20Packet%20Teva%209-30-2020.pdf.

82. According to the House Report, Teva's internal data demonstrates that its price increases cannot be explained by rebates, discounts, or other fees paid to PBMs or other entities in the pharmacy distribution chain. Indeed, Teva's net revenue (after such rebates and discounts) increased from 2009 to 2017.

83. The House Oversight Committee also found that "Teva invested only a small portion of its Copaxone revenue in further research and development to help Copaxone patients." It invested only $689 million in Copaxone related research and development since 1987, which is only 2% of the $34.2 billion in net U.S. revenue it has generated from Copaxone between 2002 and 2019.

84. Plaintiffs and members of the Class have borne the brunt of Teva's price increases, paying excessive amounts for their Copaxone – a critical MS medication.

2. Teva Engineers a Product Hop to Preemptively Blunt Generic Competition and Aggressively Migrates Consumers to Its 40mg Product.

85. To prepare for entry of generic versions of Copaxone into the market, Teva decided on a product switch strategy to prevent generic substitution for its 20mg Copaxone product. Teva sought to switch the market from its once-daily 20mg Copaxone to a 40mg version that was a larger dose taken three times weekly. To this end, Teva supplemented its NDA in 2013. FDA approved the 40mg version on January 28, 2014, and Teva launched it in the U.S. immediately.

86. Teva knew this tactic would prevent pharmacists from substituting generic version of 20mg GA when patients brought in prescriptions for 40mg Copaxone.

87. The House Report described Teva's price increase of its predecessor product and its ostensible patient transfer strategy as part of Teva's product hop strategy:

> In 2014, Teva introduced a 40 mg/ml formulation of Copaxone in part to extend its monopoly pricing for Copaxone by shifting patients to that formulation—which still enjoyed market exclusivity—before the 20 mg/ml formulation began facing lower-priced generic competition. To push

> patients to the 40 mg/ml formulation of Copaxone, Teva increased the price of the 20 mg/ml formulation. To press patients to make the move, Teva explored a plan to "Discontinue 20mg Financial Programs (Patient Services)," its financial assistance program for patients. Teva's strategy was successful in maintaining its profits and limiting competition. Experts estimate that the strategy cost the U.S. health care system between $4.3 and $6.5 billion in excess spending.[19]

88. The House Report reveals that Teva's objective in introducing the 40mg version was as a "generic defense strategy."[20] As Teva put it, "our business strategy for Copaxone® relies heavily on the successful introduction of a three-times-a week product and the migration of a substantial percentage of current daily Copaxone® patients to this new version. The failure to achieve our objectives for the new version would likely have a material adverse effect on our financial results and cash flow."[21]

89. Indeed, Teva knew there was "no supporting data for the selected dose or dosing regimen." In fact, Teva refrained from developing a once per week 40mg formulation (which would have been more convenient than a three-times-weekly dose) for fear that it would not serve its purpose of blocking generic conversion – i.e., patients might opt to take two doses of cheaper 20mg generic GA once per week rather than Teva's expensive 40mg product.[22]

90. As Teva struggled to find a viable clinical justification for the three-times-a-week dosing regimen, many of Teva's own scientists opposed the decision to pursue this dosing frequency: one scientist wrote that Teva's Innovative Research and Development management was "strongly against" Teva's study into the less-frequent dosing of Copaxone "since it has no scientific rationale/value." Despite the lack of a scientific rationale, Teva recognized that "such a

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[19] House Report.

[20] *Id.*

[21] *Id.*

[22] *Id.*

study has its business value."[23] In other words, Teva's effort to shift the market from 20mg Copaxone to the 40mg formulation was pretextual and implemented solely as another barrier to generic GA competition.

91. To ensure success of this generic defense strategy, Teva manipulated prices by pricing its new (and purportedly better) 40 mg product *lower* than its older 20 mg product and raising the price of the 20 mg product. And Teva leveraged its market power by coercing PBMs by conditioning the receipt of rebates for the 20 mg product on the PBMs adding the 40 mg product to formularies.

92. Sandoz 20mg launched its generic GA product on June 15, 2015.[24] But by that time, Teva had shifted a vast number of its U.S. Copaxone users to its 40mg formulations. Sandoz's generic entry into the market with its 20mg formulation thus had little effect because, as FDA itself has stated, Teva had, by that time, "vigorously convert[ed]" patients to Teva's 40mg formulation."

93. Teva subsequently announced in its second-quarter 2016 earnings call, that it had succeeded in migrating 83% of U.S. Copaxone users to its 40mg dose.[25]

94. By shifting patients from the 20mg to the 40mg Copaxone formulation, Teva maintained more than $3 billion in annual net revenue from 2015 to 2017, despite competition from Sandoz's 20mg generic GA beginning in mid-2015 and Mylan's 20mg and 40mg generic GA in late-2017.[26]

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[23] *Id.*

[24] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/090218Orig1s000.pdf (Sandoz FDA Approval Package).

[25] Jonathan Gardner, "*Teva Holds Cracking Door on Copaxone Generics*," Evaluate Vantage (Aug. 25, 2016), https://www.evaluate.com/vantage/articles/news/teva-holds-cracking-door-copaxone-generics.

[26] House Report.

3. Teva Files Eight Citizen Petitions to Forestall Generic Competition; FDA Approves Sandoz's 20mg ANDA and, Subsequently, Mylan's 20 and 40mg ANDA.

95. Teva also concurrently filed a total of eight citizen petitions between September 2008 and April 2015.[27]

96. In the petitions, all of which were incorporated into the Eighth Petition by reference, Teva requested that FDA "consider new scientific information and refrain from approving any abbreviated new drug application until certain conditions are met."[28]

97. FDA eventually denied Teva's requested relief in its citizen petitions, concluding that none of the information Teva argued was required for generic Copaxone ANDA approval was in fact required.[29] FDA found that the experiments and data submitted by Teva "did not provide useful information relevant to the issue of the approvability of an ANDA referencing Copaxone."

98. The same day that FDA denied the citizen petitions, on April 16, 2015, FDA approved Sandoz's ANDA 090218 for a generic formulation of generic GA 20mg (marketed as Glatopa®). But, as noted above, Teva had already shifted the market to its 40mg Copaxone,

[27] Docket No. FDA-2008-P-0529, received on September 26, 2008, and responded to on March 25, 2009 (First Petition); Docket No. FDA-2009-P-0555, received on November 13, 2009, and responded to on May 11, 2010 (including Teva's comment thereto submitted on May 10, 2010) (Second Petition); Docket No. FDA-2010-P-0642, received on December 10, 2010, and responded to on June 8, 2011 (including the supplement thereto submitted on February 22, 2011) (Third Petition); Docket No. FDA-2012-P-0555, received on June 4, 2012, and responded to on November 30, 2012 (Fourth Petition); Docket No. FDA-2013-P-1128, received on September 12, 2013, and withdrawn by Teva on January 6, 2014 (Fifth Petition); Docket No. FDA-2013-P-1641, received on December 5, 2013, and responded to on May 2, 2014 (including the supplements thereto submitted on January 27, 2014, March 10, 2014, and May 2, 2014) (Sixth Petition); and Docket No. FDA-2014-P-0933, received on July 3, 2014, and responded to on November 26, 2014 (including the supplements thereto submitted on July 17, 2014, August 12, 2014, and November 13, 2014) (Seventh Petition); Docket No. FDA-2015-P-1050, received on April 1, 2015 (Eighth Petition). Teva withdrew the Fifth Petition before FDA issued a response.

[28] Eighth Petition.

[29] FDA CP Response at 43.

thereby maintaining billions of dollars in sales at the expense of Plaintiffs and members of the class.

99. It is widely known that FDA will postpone approval of an ANDA until any associated citizens petitions are resolved. Even Teva acknowledged that citizens petitions "are almost never granted," lending further credence to the fact that it filed so many in order to delay generic approval. In fact, it was not until April 16, 2015, the same day that the last of Teva's citizen's petitions was denied, that the first generic Copaxone product was approved. At least one antitrust scholar has described Teva's flurry of citizens petitions as a "particularly glaring example of a company's aggressive use of the citizens petition process."

4. Teva Loses Its Bid to Use Its Five Patents to Protect 40mg Brand Copaxone from Generic Competition.

100. Teva listed five patents in the Orange Book to cover its 40mg Copaxone product, all of which, on their face, were due to expire in August 2030.[30]

101. Teva intended to use the purported "new" 40mg formulation and weak method Copaxone Patents and process patents to extend its monopoly and continue to effectively foreclose generic Copaxone competition.

102. Indeed, Teva stated in its Form-20F for the fiscal year ended December 31, 2013: "our business strategy for Copaxone® relies heavily on the successful introduction of a three-times-a week product and the migration of a substantial percentage of current daily Copaxone®

[30] U.S. Patent Nos. 8,232,250; 8,399,413; 8,969,302; 9,155,776 ; and 9,402,874 (individually, the '250, '413, '302, '776 and '874 patents, respectively) (collectively, "Copaxone Patents"). Teva also obtained two non-Orange Book patents for the 40mg formulation relating to the process of manufacturing glatiramer acetate, with anticipated expiries in 2035: U.S. Patent Nos. 9,155,775 ('775 patent) and 9,763,993 ('993 patent).

patients to this new version. The failure to achieve our objectives for the new version would likely have a material adverse effect on our financial results and cash flow."[31]

103. Following its successful product switch from a 20mg version to a 40mg version, Teva continued with its exclusionary plan, filing lawsuits between October 2014 and November 2015 (later consolidated) in the District of Delaware against five of the would be generic GA manufacturers who filed generic GA 40mg ANDAs and submitted Paragraph IV certifications challenging several of the Copaxone (40mg) patents ('250, '413, '302 and '776): Sandoz, Amneal, Dr. Reddy's, Mylan (in partnership with Natco), Synthon. Teva filed these suits without regard to the merits of their infringement claims or the validity of their patents, but for the purpose of delaying generic competition.

104. After a seven day bench trial, the District Court (Sleet, J.), dealt Teva a resounding rebuke, invalidating four Copaxone Patents ('250, '413, '302 and '776) as obvious, under 35 U.S.C. § 103. The court concluded:

> [T]he dosing regimen disclosed in patent directed at drug used to treat patients with relapsing forms of multiple sclerosis was obvious; patent described thrice-weekly 40mg injection, 20mg and 40mg dose sizes had already been shown to be effective and safe, a daily 20mg injection had already been approved, and prior art suggested that less frequent injections were just as effective as daily injections and that less frequent injections improved patient adherence and reduced adverse reactions, i.e., that limitations in multiple sclerosis drug patent, that claimed less-frequent dosing regimen would improve tolerability and reduce adverse reactions, were obvious was not clearly erroneous; prior art had disclosed benefits of less frequent injections, and it was common sense that fewer injections would lead to fewer injection-related reactions.

[31] Teva Pharmaceutical Industries Limited, Form-20F, for the fiscal year ended December 31, 2013, at 63, https://www.annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2013.pdf.

105. The District Court offered a stinging opinion on four of the Teva Copaxone patents: "The court sees the '250, '413, '302, and '776 patents as nothing more than 'life-cycle management' – an attempt to continue to monopolize a multi-billion-dollar market for a blockbuster drug."[32]

106. In October 2018, after Mylan had launched generic versions of both Copaxone strengths, the Federal Circuit affirmed the district court's finding invalidating all asserted claims of the four Copaxone patents at issue as obvious. On the same day, the Federal Circuit also affirmed[33] rulings of the Patent Appeal and Trial Board (PTAB) invalidating the '250, '413 and '302 Copaxone patents as a result of three *inter partes* review (IPR) filings by Mylan.[34] In substance: every tribunal to review Teva's Copaxone patents found the 40mg three-times-a-week dosage regimen obvious over the prior art.

107. Teva also filed a suit against nine generic glatiramer acetate ANDA filers on December 19, 2016 in the United States District Court for the District of Delaware.[35] On May 1, 2017, the Court entered a *Stipulation and Order Dismissing With Prejudice Claims and Counterclaims Regarding U.S. Patent No. 9,402,874*.[36] In early 2020, Teva requested removal of the '874 Patent from the Orange Book, following court decisions on other patents directed to

[32] *In re Copaxone Consolidate Cases*, Civil Action No. 14-1171-GMS, 2017 U.S. Dist. LEXIS 12168 (D. Del. Jan. 30, 2017). In addition, Teva brought a separate case on the '775 and '993 patents against the five generics that was consolidated No. 14-1171, but which was not part of the bench trial and January 30, 2017 decision. Teva filed a stipulation of dismissal with prejudice as to this separate case on March 29, 2019.

[33] *Yeda Research & Development Co. v. Mylan Pharmaceuticals Inc.*, Nos. 17-1594, 17-1595, 17-1596, 906 F.3d 1031, 2018 WL 4938974 (Fed. Cir. Oct. 12, 2018) (Reyna, J.).

[34] IPR2015-00830, IPR2015-00643, and IPR2015-00644.

[35] *See In re: Copaxone*, No. 1:16-cv-01267-CFC (D. Del. Dec. 19, 2016), Dkt. No. 1.

[36] *See id*. (D. Del. May 1, 2017), Dkt. No. 74.

methods of using Copaxone.[37] On March 29, 2019, the Court entered a *Stipulation of Dismissal of Claims, Counterclaims, and Affirmative Defenses*, with prejudice, regarding the '775 and '993 patents.[38]

108. In short, Teva used baseless patent litigation against its generic competitors as a weapon to try to delay generic competition.

5. Mylan Receives FDA Final Approval For 40mg and 20 mg and Launches.

109. Following the district court win, FDA approved Mylan's ANDA for generic Copaxone 40-mg three-times-a-week treatment on October 3, 2017 and its generic version of the 20mg formulation, a once daily injection. Mylan thus became the first ANDA applicant to obtain approval of a generic version of 40 mg Copaxone®.[39] Mylan launched both generic formulations on October 5, 2017. As described below, Teva's exclusionary scheme prevented uptake of generic Copaxone, despite Mylan reducing the list price of its generic Copaxone 40 mg product by 60% in July 2018.

VI. FACTS GIVING RISE TO PLAINTIFF'S CLAIMS

A. Teva's Exclusionary House Brand Strategy with PBMs and PBM-Owned Specialty Pharmacies

110. Teva knew it stood to lose hundreds of millions of dollars when FDA approved a generic version of Copaxone.

111. Teva was closely monitoring the market, obtaining market intelligence in order to determine precisely which generic(s) would enter and when. As the entry of Mylan and Sandoz's

[37] *See Teva Pharm. USA, Inc. v. FDA et al.*, No. 1:20-cv-00808-BAH (D.D.C. July 16, 2020) Dkt. No. 41-1 (Declaration of Coleman Ragan).

[38] *See In re: Copaxone*, No. 1:16-cv-01267-CFC (D. Del. Mar. 29, 2019), Dkt. No. 264-1.

[39] Letter from Vincent Sansone, Acting Deputy Director, CDER, to Mylan Pharmaceuticals Inc., dated October 3, 2017, https://www.accessdata.fda.gov/drugsatfda_docs/appletter /2017/206936Orig 1s000ltr.pdf.

competing generic GA product become an increasing reality, Teva unleashed the latest tactic in its arsenal to prevent and stymie competition.

112. In order to unlawfully thwart the uptake of generic 40 mg GA, first from Mylan and then from Sandoz, Teva designed and implemented a multi-part exclusionary scheme, which leveraged its dominant market position to ensure that automatic substitution laws would have little to no effect once generic entry occurred.

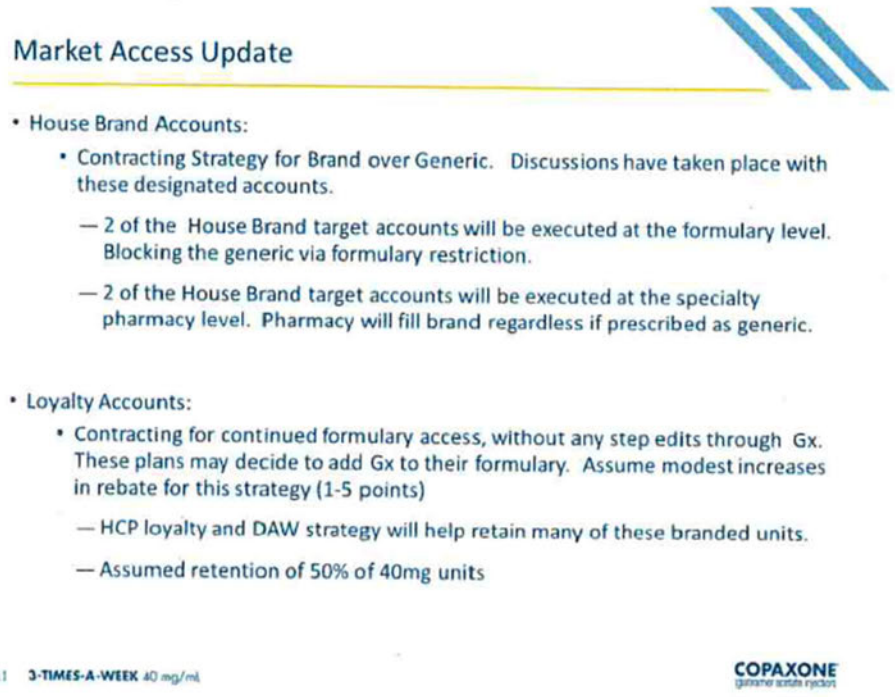
113. Teva referred to one part of its exclusionary scheme internally as the "House Brand" Strategy. The scheme consisted of anticompetitive exclusionary contracts with two types of entities: (1) PBMs and (2) PBM-owned specialty pharmacies. The scheme aimed to ensure that automatic substitution laws, which would have resulted in the substitution of Teva's brand Copaxone product for Mylan and Sandoz's generic Copaxone product, would have virtually no effect. Instead, by contracting with intermediaries, Teva was able to ensure that its brand Copaxone product would be covered and dispensed, even though Mylan and Sandoz were offering less-expensive generic versions.

114. First, Teva contracted with PBMs to block coverage of generic GA through what is referred to as a formulary restriction. Teva described this as "executed at the formulary level" and "blocking the generic via formulary restrictions." Pursuant to these agreements, Teva promised additional rebates to the PBMs in exchange for filling all "'glatirmer' or Copaxone scripts with Copaxone," rather than the generic. But the strategy went further—it forced PBMs to exclude generic GA. If the specialty pharmacy dispensed generic GA, the PBM would lose extra Copaxone-related rebates from Teva.

115. Second, this all-or-nothing rebate approach was combined with contracts with specialty pharmacies affiliated with the PBMs that required the pharmacy to replace any generic

Copaxone prescriptions with the brand, even if the prescription specifically requested that it be filled with a generic version.

116. In an internal slide to its Board of Directors, Teva described the House Brand scheme as follows: one part of its strategy would be "executed at the formulary level" by "blocking the generic via formulary restriction" and the second part of its strategy would be "executed at the specialty pharmacy level" where the [p]harmacy will fill brand regardless if prescribed as generic."



117. Teva's Executive Vice President for North America offered an even more direct explanation of precisely how the scheme operated to thwart generic competition: "[PBM] is getting an additional rebate to fill all "glatiramer' or Copaxone scripts with Copaxone. . .if a doctor orders generic glatiramer or the pharmacy benefit mandates it be filled as a generic, it will come in a plain box with Copaxone inside. Win-win for all. . .[Specialty Pharmacy] only ships brand Copaxone

no matter how it is written or what the formulary states. This is why this [putting Copaxone on non-preferred tier] has little impact."

On Jan 31, 2018, at 3:56 PM, Brendan O'Grady Highly Confidential wrote:

Because PBM is getting an additional rebate to fill all "glatiramer" or Copaxone scripts with Copaxone...if a doctor orders generic glatiramer or the pharmacy benefit mandates it be filled as a generic, it will come in a plain box with Copaxone inside. Win-win for all...

Best regards,

<image001.png> Brendan P. O'Grady EVP and Head of North America
Highly Confidential

On Jan 31, 2018, at 4:02 PM, Brendan O'Grady Highly Confidential wrote:

No as last I understood, Specialty Pharmacy only ships brand Copaxone no matter how it is written or what the formulary states. That is why this has little impact. Then again, my knowledge may be dated.

Best regards,

<image001.png> Brendan P. O'Grady EVP and Head of North America
Highly Confidential

118. As a direct result of Teva's exclusionary scheme, automatic substitution laws could not operate as they were intended to, and generic GA could not compete with the brand on price – even though it was less expensive and would have saved Plaintiffs and members of the class millions of dollars in overcharges. For example, in July 2018, Mylan reduced its list price for 40 mg Copaxone by 60%, but the price reduction hardly impacted sales. Teva's exclusionary tactics were successful in preventing competition, at the expense of third-party payors. According to Mylan, its price reduction "had hardly any impact on Mylan's sales" because Teva's contracts with

PBMs and specialty pharmacies mandated substitution of Teva's 40mg product. Mylan put it simply: "there is no price Mylan could go to that would change the equation."[40]

119. As a result, Plaintiffs and Class Members have been forced to pay supracompetitive prices for brand Copaxone, and have been prevented from buying larger quantities of the generic GA, despite the availability of less-expensive generic GA.

120. The Staff Report and certain documents cited therein suggest that one means Teva used to induce PBMs and specialty pharmacies to accept the exclusionary contracts was by paying rebates. However, Teva's rebates (or more precisely the impact of those rebates on pricing) was not the predominant mechanism of exclusion. Indeed, Plaintiffs allege they were denied the ability purchase more affordable generic Copaxone because of Teva's exclusionary scheme. Plaintiffs allege that, to prevent generic competition, Teva leveraged its monopoly power to block generic Copaxone from formularies and to ban generic Copaxone from being shipped. As a result of Teva's exclusionary conduct, generic manufacturers were denied the opportunity to compete. In addition, Teva effectively prevented purchasers such as Plaintiffs and other class members from having any choice with respect to the product they purchased. The lack of competition and choice caused harm to Plaintiffs and class members, and there is no cognizable, non-pretextual, procompetitive justification for Teva's exclusionary conduct that would outweigh its harmful effects. Teva's exclusionary contracts were part of an overarching scheme to suppress generic competition.

B. Teva's False and Misleading "DAW" Campaign

121. Teva employs a team of sales representatives who regularly visit and communicate with medical professionals and staff across the country to market Copaxone and persuade them to

[40] *See Mylan Pharm. Inc. v. Teva Pharms. USA, Inc., et al*., No. 6:21-cv-00072-CEM-DCI (D. Fla. January 8, 2021) Dkt. No. 1 "Mylan Complt."), at ¶ 7.

prescribe it. Teva also promotes Copaxone through its Shared Solutions patient support hub and nursing support platform, where it provides copay support, patient training, nursing support and other resources. Shared Solutions personnel also visit and communicate with medical professionals and staff in addition to MS patients.

122. In order to circumvent the automatic substitution laws and push doctors to write prescriptions for Copaxone instead of generic GA, Teva engaged in a campaign of false and misleading marketing statements about generic GA. Teva began this campaign before Mylan launched its 40 mg GA and continued after Mylan's launch.

123. First, Teva, through its sales representatives, Shared Solutions patient support personnel and nursing support platform, made false statements to medical practitioners and patients about the efficacy of generic GA. Teva and/or its sales representatives falsely stated, without evidence or any valid scientific basis, that generic GA is only 80% or 85% as effective as Copaxone. Teva knew these statements to be false since FDA has determined that generic GA is an AP-rated equivalent substitute to Copaxone. Teva also knew, at the time these statements were made, that there were no comparative efficacy trials of Mylan's generic GA to Copaxone.

124. According to Mylan, because this information was disseminated through portals that prescribers and patients relied on: (i) its representatives consistently encountered medical professionals throughout the country who would not speak to Mylan representatives as a result of this misinformation campaign or believed that generic GA was only 80% or 85% as effective as Copaxone; (ii) these statements had been disseminated widely among those who prescribe GA; and (iii) a significant portion of those prescribers attributed the statements to Teva and its sales representatives. As a result, Mylan could not correct this misinformation.

125. Second, Teva's sales representatives and Shared Solutions personnel made false and misleading statements to medical professionals and patients that Mylan did not offer copay support for its generic GA product. Teva knew these representations were false or misleading in that it had no support for the statements and knew or should have known that Mylan had included information about its copay assistance in its press release in October 2017 announcing the launch of its product. Mylan announced that it would offer copay assistance to eligible patients through its MS Advocate program. Teva continued to make the false and misleading statements about copay support after this date.

126. According to Mylan, because this information was disseminated through portals that prescribers and patients relied on: (i) its representatives encountered medical professionals and staff across the country who would not speak to Mylan representatives as a result of this misinformation campaign or believed that Mylan does not offer copay support for its generic GA product; (ii) these statements had been disseminated widely among those who prescribe GA; and (iii) a significant portion of those prescribers attributed the statements to Teva and its sales representatives. As a result, Mylan could not correct this misinformation.

127. Third, Teva's sales representatives and Shared Solutions personnel made false and misleading statements to medical professionals and patients that Mylan did not provide patient training and nursing support for its generic GA product. Teva knew that physicians and patients valued patient training and nursing support services, which it relied on to drive additional sales of Copaxone. For example, Teva's 2012-2014 workplan reported that its $29 million "investment" in patient services in 2011 had "generated" $363 million in sales. The workplan emphasized that this expenditure reflected a significant return on investment: "ROI of 1152%."[41] Teva executives

[41] House Report.

estimated in 2017 that conducting an additional 1,200 injection trainings would cost the company $250,000, but "net $2.5M [million] in incremental sales."[42] By claiming that Mylan did not provide these services, Teva could retain a significant share of Copaxone sales by dissuading physicians and patients from switching to lower priced generic GA. Indeed, Teva viewed its Shared Solutions services as "key activities to defend Copaxone Against Generic erosion."[43] However, Teva knew these representations were false or misleading in that it had no support for the statements and knew or should have known that Mylan had included information about its patient training and nursing support in its press release in October 2017 announcing the launch of its product. Mylan announced that it would offer "in-home injection training," "a 24/7 patient support center," and "ongoing support from an MS-experienced nurse" through its MS Advocate program. Teva continued to make the false and misleading statements about copay support after this date.

128. According to Mylan, because this information was disseminated through portals that prescribers and patients relied on: (i) its representatives encountered medical professionals and staff across the country who would not speak to Mylan representatives as a result of this misinformation campaign or believed that Mylan does not offer patient training and nursing support for its generic GA product; (ii) these statements had been disseminated widely among those who prescribe GA; and (iii) a significant portion of those prescribers attributed the statements to Teva and its sales representatives. As a result, Mylan could not correct this misinformation.

129. Finally, Teva's sales representatives and Shared Solutions personnel made false and misleading statements to medical professionals and patients that Mylan's generic GA product was a biologic or biosimilar and therefore a more complex drug and not the same medication as

[42] *Id.*

[43] *Id.*

Copaxone. Teva knew these representations were false or misleading in that Mylan's product is not a biologic or biosimilar and has been deemed by FDA to be an AP-rated equivalent to Copaxone.

130. According to Mylan, because this information was disseminated through portals that prescribers and patients relied on its representatives encountered medical professionals throughout the country who would not speak to Mylan representatives as a result of this misinformation campaign or believed that Mylan's generic GA product is a biologic or biosimilar or otherwise materially different or more complex than Copaxone and those medical professionals were told this misinformation by Teva.[44] As a result, Mylan could not correct this misinformation.

131. All of the above-described marketing statements were made without support or evidence or valid scientific basis and despite Teva's knowledge that no support existed for these statements. Although medical professionals are sophisticated decisionmakers, they rely on drug manufacturers for information related to drug products, and it is reasonable for healthcare professionals to expect that a drug manufacturer will not make false and misleading representations with no basis, support or evidence. The fact that Teva did so here prevented Mylan from correcting the false information. Moreover, patients necessarily rely on the drug manufacturer to provide information about medications. Teva did not simply make superiority claims about its product versus generic Copaxone; rather, it made false and baseless statements to patients and healthcare professionals.

[44] This false and misleading campaign culminated in another attempt by Teva to abuse the court processes. Teva filed a lawsuit in March 2020 seeking to have Copaxone classified as a biologic in yet another attempt to thwart generic substitution. Teva argued that a generic would have to be deemed "interchangeable" under the BPCIA standards. The district court dismissed this baseless suit in December 2020, deeming it as "yet another effort to stifle Copaxone competitors" and recognizing that Teva's arguments contradicted positions it had previously taken.

132. According to Mylan, Teva's misrepresentations and false statements had so thoroughly influenced healthcare professionals that many refused to even talk to Mylan's representatives trying to correct them and/or argued against Mylan's representatives using Teva's false statements.

133. The purpose of Teva's campaign of false and misleading promotional statements was to prevent uptake of generic versions of GA by persuading doctors to write "DAW" prescriptions for Copaxone so that the pharmacist could not substitute less expensive generic GA for those prescriptions, thereby circumventing automatic substitution laws.

134. Teva knew that its DAW campaign was an important part of its scheme to thwart generic competition, as reflected in its strategy documents. For example, a January 2017 Teva presentation titled "At-Risk Gx Readiness" states, "HCP [healthcare professional] loyalty and DAW strategy will help retain many of these branded units."[45]

135. Teva leveraged its Shared Solutions program to influence patients with its DAW campaign. An August 2017 internal analysis showed that DAW was written on 87% of Copaxone 40 mg prescriptions requested through the Shared Solutions service.[46]

136. Teva continued this part of its scheme after Mylan launched its generic GA. A Board presentation from October 2017 includes Teva's "Key Activities to Defend Against Generic Erosion."[47] These "Key Activities" included "Sales force proactively messages to HCP customers the need for "Dispense as Written" on all new Rx and refills" as well as "[o]utbound efforts to 40mg patients through Shared Solutions, which included "[e]mails to all patients with DAW

[45] House Report Document Packet, doc no. 53.

[46] House Report.

[47] House Report Document Packet, doc no. 44.

messaging[.]"[48] Teva was also able to get current patient lists for practitioners to "proactively" write DAW on prescriptions.[49] Likewise, an August 2018 presentation stated, "reinforce DAW on every call."[50]

137. Because of its false and misleading statements to healthcare professionals, Teva succeeded in circumventing automatic substitution and preventing uptake of generic GA. The DAW prescription rate for Copaxone was approximately 13.5% in the period leading up to Mylan's generic launch, and it rose to 77% by February 2018. An August 2018 email from Teva's Executive Vice President for North America stated that "[t]he DAW campaign combined with the legacy and house brand access strategy has paid great dividends." Usually, a generic will capture close to 90% of the market within a year of its launch. Here, through its exclusionary scheme, Teva was able to shut out generics from as much as 77% of the market several months after generic entry.

138. Following the entry of Mylan's generic GA formulations in October 2017 and Sandoz's generic 40mg GA product in February 2018, Teva continued to maintain more than 50% of the market despite the list price of Copaxone being higher than the prices of the generics.

[48] *Id.*

[49] *Id.*

[50] House Report.

C. Teva's Anticompetitive Copay "Couponing" Strategy and Illegal Kickback Scheme

139. As another aspect of Teva's anticompetitive scheme, Teva utilized a "coupon" program which, together with other aspects of its scheme, effectively inflated the price of Copaxone and allowed Teva to maintain its high prices to health plans.

140. Health plans use deductibles, copayments, coinsurance and other cost-sharing mechanisms to limit healthcare spending. Thus, cost-sharing mechanisms effectively lower costs for health plan payors. Teva worked to circumvent the incentives and price pressure created as a result of cost-sharing obligations by removing plan members' copay obligations, thereby removing their incentives to choose the A-rated generic alternative. Since the consumer typically bears only a small portion of the drug's total cost, this "coupon" to the consumer allows Teva to maintain and increase marketshare *while artificially increasing prices above the levels that would have existed in a competitive market*.

141. Specifically, Teva provided patients with "coupons" that covered all or some of the cost of their co-pays through a service called "Copaxone Co-Pay Solutions." So, when a health plan member filled a Copaxone prescription, the pharmacy would accept the coupon in lieu of the member's co-pay obligation, and Teva would pay the pharmacy for the value of the coupon. The coupons thus allowed Teva to charge supracompetitive prices for Copaxone without provoking a natural market response; this resulted in payors, including Plaintiffs and Class members, having to cover *more* purchases of brand Copaxone at higher costs than they would have paid in the absence of Teva's unlawful conduct.

142. Teva used its "coupon" program to help create a captive market that allowed Teva to preserve its Copaxone monopoly and supracompetitive profits while significantly limiting generic uptake compared to what would be expected under competitive conditions. Teva's coupon program has caused payors, like Plaintiffs and the Class member, to pay millions of dollars more

for Copaxone than lower cost generic GA that would have been prescribed absent Teva's anticompetitive conduct. The "coupon" program allowed Teva to maintain its high prices to health plans by effectively eliminating cost-sharing obligations for plan members.

143. Teva's internal documents show that its co-pay plan resulted in large returns for Teva in Copaxone revenue. For example, Teva's 2008 Copaxone Work Plan estimated that Teva would spend approximately $70 million on "Private Insurance Financial Assistance" between 2008 and 2011, resulting in sales of 198,930 units of Copaxone. Assuming a list price of $1,886 per unit (the price of Copaxone on the date of the presentation), these sales were worth at least $373,484,580 – a 433% return on investment. These projections were conservative. In its Workplan for 2012 to 2014, Teva's co-pay program had a reported average return on investment of 451% for commercial patients. In 2017, Teva estimated that a patient on the program was 15% more likely to stay on the drug for 12 months than a patient that was not on the program. Keeping patients on the program was key for Teva because it allowed them to charge supracompetitive prices to the respective consumer's insurer or health plan.

144. Internal documents indicate that Teva collected $257.5 million in net revenue from its $56.4 million in expenditures on commercial programs in 2014, with $148.2 million in net revenue from $68.4 million in program expenditures in 2015.[51] Put simply, Teva's "coupon" scheme paid dividends. It allowed Teva to maintain supracompetitive prices for Copaxone without losing substantial sales volume, undermined generic substitution, and forced payors, like Plaintiffs and the Class members, to continue paying for the more expensive brand Copaxone in the face of supracompetitive prices. Indeed, an HHS OIG Advisory bulletin has explained harm resulting from programs like Teva's:

[51] House Report.

> Subsidies provided by traditional pharmaceutical manufacturer PAPs [patient assistance programs] have the practical effect of locking beneficiaries into the manufacturer's product .... [C]ost-sharing subsidies can be very profitable for manufacturers, providing additional incentives for abuse. So long as the manufacturer's sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit. These profits can be considerable, especially for expensive drugs for chronic conditions.[52]

145. Teva was no stranger to this type of scheme, which it has also employed with non-commercial plans. In fact, Teva employed a similar scheme involving kickbacks to do the same thing with respect to Medicare plans. Teva effectively eliminated cost-sharing obligations for Medicare recipients by funneling money through third-party foundations which it knew would be directed to pay those co-pays. Teva engaged in this conduct for at least a decade, and according to the House Report, it continued until at least 2018.

146. The Department of Justice filed suit against Teva in August 2020 alleging that "Teva knowingly and willfully violated the anti-kickback statute, 42 U.S.C. § 1320a-7b(b), by paying over $300 million to two third-party foundations, Chronic Disease Fund ("CDF") and The Assistance Fund ("TAF"), to cover the Medicare copay obligations of Copaxone patients."

147. Although Teva claimed these payments were "donations," Teva made payments only to these two foundations because "it had assurance that its money would go to patients taking . . . Copaxone" and not to patients taking other drugs.

148. The purpose of Teva's payments to the foundations, like its "coupon" program, was to allow Teva to keep the price of Copaxone high by disincentivizing patients from switching to a generic alternative. This combined with Teva's other anticompetitive acts suppressed generic uptake and caused Plaintiffs and the class to continue paying inflated prices for GA.

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[52] HS-OIG's 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70626 (Nov. 22, 2005).

149. A January 2018 internal Teva email cited in the House Report explains how Teva's use of the kickbacks prevented generic uptake and kept prices high for insurers. The email discusses an insurer's decision to move Copaxone 40mg to non-preferred status for both Commercial and Medicare Part D plans, covering approximately 15 million and 1 million lives respectively. Teva's Executive Vice President for North America explained why the insurer's attempt to facilitate conversion to less expensive generic GA failed: "Also, the NP [non-preferred] status means little as we buy the patients [sic] copay down to zero anyway. Unless they NDC block Copaxone 40mg, we are fine. . . the actual impact is very low. . . ."[53]

150. Teva continued making these "donations" at least into 2018. The House Report notes that Teva made $23,286,429 in "charitable cash contributions in connection with Copaxone" in 2018.[54] In drafts of its planning documents for 2018, Teva noted that "eliminating its 'Medicare Donation' to third-party foundations would cost Teva up to $261 million in Copaxone sales."[55]

151. Through its "coupons" and "donations" Teva was able to circumvent the market effect of cost-sharing obligations for private health plan members and Medicare recipients. This allowed it to charge supracompetitive prices to all payors, including Plaintiffs and members of the Class.

VII. MARKET POWER AND MARKET DEFINITION

152. At all relevant times, Teva has maintained monopoly power over the glatiramer acetate market: it had the power to raise and/or maintain the price of glatiramer acetate at supra-

[53] House Report; House Report, Document packet.

[54] House Report.

[55] *Id.*

competitive levels without losing substantial sales to other products, except for AP-rated generic versions of Copaxone, to make the supracompetitive prices unprofitable.

153. Direct evidence of Teva's market power includes the following: (a) from 2013 to 2018, the per-unit manufacturing cost for Copaxone was less than 3% of the net price of the drug, i.e., the price after adjusting for rebates and discounts; (b) when generic Copaxone eventually entered the market, it took a portion of brand Copaxone's unit sales; (c) Teva never lost Copaxone sales in response to pricing of other brand or generic drugs, except for AP-rated generic Copaxone; (d) Teva never lowered the price of Copaxone to the competitive level in response to pricing of other brand or generic drugs; and (e) from 2006 to 2015, prior to generic entry, Defendants profitably raised the price of Copaxone 20mg by approximately 350%.

154. To the extent that Plaintiffs and the class are required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is Copaxone and AP-rated glatiramer acetate generics.

155. Brand Copaxone is therapeutically differentiated from all RRMS products other than AP-rated generic versions of Copaxone. The availability of other RRMS disease-modifying treatments has not constrained Teva. Teva has continually increased the prices for Copaxone over the years, even when new RRMS injectable disease-modifying therapies were approved by the FDA.

156. Only the market entry of a competing, AP-rated equivalent generic version of Copaxone and the absence of Teva's anticompetitive conduct would make Teva unable to profitably maintain its prices for Copaxone without losing substantial sales.

157. Teva has used its market power to foreclose or otherwise adversely affect competition in the market for FDA-approved AP-rated glatiramer acetate drug products by—

among other unlawful tactics—engaging in an anticompetitive coupon and kickback scheme to keep Copaxone prices high, preventing uptake of generic versions of Copaxone by entering into anticompetitive agreements to block generics from formulary access and prevent generic substitution at the specialty pharmacies, and engaging in a campaign of false and misleading disinformation about generic GA products to prevent uptake.

158. Teva's conduct has forced third-party payors to purchase Copaxone at artificially high and noncompetitive price levels and denied them the availability of a lower cost generic glatiramer acetate product.

159. Teva has had a significant incentive to maintain its monopoly over glatiramer acetate and keep prices artificially high.

160. The relevant geographic market is the United States, the District of Columbia, and the U.S. territories.

161. At all relevant times, Teva enjoyed high barriers to entry with respect to the above-defined relevant market due to patent protection, the high cost of entry and expansion, expenditures in marketing and physician detailing, and state statutes that require prescriptions for the purchase of the products at issue and restrict substitution of those products at the pharmacy counter. The products in this market require significant investments of time and money to design, develop, and distribute. In addition, the market requires government approvals to enter and/or the drugs at issue may be covered by patents or other forms of intellectual property. Teva's unlawful conduct further restricted entry. Thus, during the relevant time, existing and potential market entrants could not enter and/or expand output quickly in response to Teva's higher prices or reduced output.

162. A small but significant, non-transitory price increase to Copaxone by Teva would not have caused a significant loss of sales to other drugs or products used for similar purposes, with the exception of AP-rated equivalent generic versions of glatiramer acetate.

163. Brand Copaxone does not exhibit significant, positive cross-price elasticity of demand with any other treatment for multiple sclerosis, and thus other drugs that are not AP-rated to Copaxone are not economic substitutes for, and are not reasonably interchangeable for Copaxone.

VIII. EFFECT ON INTRASTATE AND INTERSTATE COMMERCE

164. At all material times, Copaxone, manufactured and sold by Teva, was promoted, distributed, sold and/or shipped in a continuous and uninterrupted flow of commerce across state lines and sold to customers located outside its state of manufacture.

165. During the relevant time period, in connection with the purchase and sale of Copaxone, monies as well as contracts, bills, and other forms of business communications and transactions were transmitted in a continuous and uninterrupted flow across state lines.

166. During the relevant time period, various devices were used to effectuate the illegal acts described above, including United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. Teva's activities, as alleged in this complaint, were within the flow of, and have substantially affected, interstate commerce.

167. Teva's anticompetitive conduct occurred in part in trade and commerce within the states set forth herein. Teva's conduct had substantial interstate and intrastate effects because physicians within each state have been wrongfully induced into prescribing brand Copaxone instead of lower priced generic Copaxone through Teva's DAW campaign, pharmacies within each state have dispensed brand Copaxone instead of lower priced generic Copaxone through Teva's House Brand strategy, and patients and health plans within each state have been forced to

continue paying supra-competitive prices for Copaxone prescriptions, which, in the absence of Teva's anticompetitive conduct, would have been filled with lower priced generic Copaxone.

IX. ANTITRUST IMPACT

168. During the relevant time period, Plaintiffs and members of the class purchased substantial amounts of glatiramer acetate indirectly from Teva. As a result of Defendants' illegal conduct, Plaintiffs and members of the class were compelled to pay, did pay, and continue to pay artificially inflated prices for glatiramer acetate. Those prices were substantially greater than the prices that members of the class would have paid absent the illegal conduct alleged herein, because: (1) the price of branded Copaxone was artificially inflated by the Teva's illegal conduct, (2) class members were deprived of the opportunity to purchase lower-priced generic versions of Copaxone in greater quantities, which they would have done had they had the opportunity, and/or (3) the price of generic Copaxone was artificially inflated by the Teva's illegal conduct. The supracompetitive prices were paid at the point of sale, which is where Plaintiffs and the proposed class suffered antitrust impact.

169. As a consequence, Plaintiffs and members of the class have sustained substantial damages to their business and property in the form of overcharges. The full amount and forms of components of such damages will be calculated after discovery and upon proof at trial. Commonly used and well-accepted economic models can be used to measure both the extent and the amount of the supracompetitive charges to end payors such as Plaintiffs and members of the class.

170. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. According to Professor Hovenkamp, "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." Professor Hovenkamp also acknowledges that "[t]heoretically, one can calculate

the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."[56]

171. Further, the institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution are passed on to end payors. Wholesalers and retailers passed on the inflated prices of Copaxone to Plaintiffs and the Class of end-payors defined herein. Teva's anticompetitive actions enabled it to indirectly charge end-payors prices in excess of what it otherwise would have been able to charge absent its unlawful conduct. The prices were inflated as a direct and foreseeable result of Teva's anticompetitive conduct.

X. CLASS ACTION ALLEGATIONS

172. Plaintiffs bring this action on their own behalf and on behalf of all others similarly situated as a class action under Rules 23(a), 23(b)(2), and 23(b)(3) of the Federal Rules of Civil Procedure, seeking damages pursuant to the laws of the states listed below (the "Indirect Purchaser States"), and as representative of a class defined as follows:

> All third-party payors in the Indirect Purchaser States[57] and territories that paid some or all of the purchase price for Copaxone or glatiramer acetate at any time during the period from October 1, 2017 through and until the anticompetitive effects of the defendants' challenged conduct cease (the "Class Period").

173. Excluded from the class are:

a. the Defendants and their counsel, officers, directors, management, employees, subsidiaries, and affiliates;

b. all federal governmental entities;

[56] *See* H. Hovenkamp, FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE (1994) at 624.

[57] The "Indirect Purchaser States" are the states identified in Claims I-III below.

c. all judges assigned to this case and any members of their immediate families.

174. Members of the class are so numerous and widely geographically dispersed throughout the United States and its territories that joinder is impracticable. Plaintiffs believe that the class numbers in the dozens at least and is geographically spread across the nation. Further, the identities of members of the class will be readily identifiable from information and records in the possession of Teva.

175. Plaintiffs' claims are typical of the claims of members of the class. Plaintiffs and all members of the class were damaged by the same wrongful conduct by Teva, and all paid artificially inflated prices for Copaxone and were deprived of the benefits of competition from less expensive generic versions as a result of the Defendants' conduct.

176. Plaintiffs will fairly and adequately protect and represent the interests of the class. Plaintiffs' interests are coincident with, and not antagonistic to, the class.

177. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving the pharmaceutical industry.

178. Questions of law and fact common to members of the class predominate over questions, if any, that may affect only individual class members, because the Defendants have acted on grounds generally applicable to the entire class. Such generally applicable conduct is inherent in the Defendants' wrongful conduct.

179. Any plaintiff who was forced to pay a higher price in the absence of generic competition has a substantial and shared interest in proving that the higher price was the result of unlawful monopolizing conduct that is redressable by an award of damages.

180. Questions of law and fact common to the class include:

a. whether Teva unlawfully maintained monopoly power through all or part of its overarching scheme;

b. whether Teva's anticompetitive scheme suppressed generic competition to Copaxone;

c. as to those parts of Teva's challenged conduct for which such justifications may be offered, whether there exist cognizable, non-pretextual procompetitive justifications, which the Defendants' challenged conduct was the least restrictive means of achieving, that offset the harm to competition in the market in which glatiramer acetate is sold;

d. whether direct proof of Teva's monopoly power is available, and if available, whether it is sufficient to prove Teva's monopoly power without the need to also define a relevant market;

e. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

f. whether Teva's scheme, in whole or in part, has substantially affected interstate commerce;

g. whether the Teva's scheme, in whole or in part, caused antitrust injury to the business or property of Plaintiffs and members of the class in the nature of overcharges; and

h. the quantum of overcharges paid by the class in the aggregate.

181. Class action treatment is a superior method for the fair and efficient adjudication of this controversy. Among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently,

and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

182. Plaintiffs know of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XI. TEVA CONCEALED ITS UNLAWFUL CONDUCT

183. The claims of Plaintiffs and members of the class accrue each time they suffer injury as a result of Defendants'' anticompetitive conduct. Plaintiffs and members of the class were injured each time they purchased Copaxone at supracompetitive prices or purchased less generic Copaxone than they would have absent Teva's anticompetitive scheme. Each sale of brand Copaxone constituted an overt act in furtherance of Teva's continuing anticompetitive scheme.

184. Additional overt acts in furtherance of Teva's continuing misconduct include, but are not limited to: implementing and enforcing exclusionary agreements with PBMs to bar generic Copaxone from formularies; obtaining and enforcing agreements with specialty pharmacies to circumvent generic substitution laws so that the brand product is always shipped, even when generic is prescribed; falsely disparaging generic Copaxone in order to convince prescribers to write DAW on all Copaxone prescriptions; and using couponing to drive up brand sales. As a result, Plaintiffs and members of the class are entitled to recover damages on their brand Copaxone purchases within the applicable statute of limitations.

185. In addition, because Teva fraudulently concealed its unlawful conduct, Plaintiffs and the members of the class are entitled to recover damages extending back beyond the applicable

statute of limitations in relation to the filing of this complaint. Plaintiffs and the members of the class had no knowledge of Teva's unlawful scheme and could not have discovered the scheme through the exercise of reasonable diligence prior to the applicable statute of limitations in relation to the filing of this complaint.

186. Plaintiffs and the members of the class could not have known that Teva was entering into exclusionary agreements with PBMs and specialty pharmacies to bar generic Copaxone until the House Committee published its report on September 30, 2020. Teva took steps to keep these anticompetitive agreements secret. This included senior Teva executives warning subordinates that the exclusionary agreements with PBMs and specialty pharmacies should not be shared even internally with other Teva employees due to their "confidential nature." Moreover, internal communications discussing the exclusionary contracts were prominently stamped with the admonition: "DO NOT COPY. DO NOT DISTRIBUTE."

187. Similarly, Plaintiffs and the members of the class could not have known about Teva's "Dispense as Written" campaign until the issuance of the Staff Report. And only subsequently, when Mylan filed its lawsuit against Teva on June 29, 2021, did it come to light that Teva's "Dispense as Written" campaign was punctuated by a misinformation campaign regarding generic Copaxone, including untrue statements about the efficacy of the generic products.

188. It was not until the House Committee issued its report a few weeks later, on September 30, 2020, that Teva's exclusionary contracts and other key aspects of Teva's monopolization scheme began to come to light. Notably, the Staff Report was based on the House Committee's review of over 300,000 pages of internal, nonpublic documents and communications produced by Teva to the Committee in response to a formal request. Similarly, the Mylan

complaint filed in June 2021 set forth information that could not have been known by Plaintiffs prior to the filing of that action.

189. Teva's illegal monopolization scheme was also inherently self-concealing because, as Defendants knew, its disclosure would have exposed it to civil liability and governmental enforcement actions, as in fact occurred when the scheme came to light. *See e.g.*, *Mylan Pharmaceuticals Inc. v. Teva Pharmaceuticals Industries Ltd, et al.*, case no. 21-cv-13087 (D.N.J.) (complaint filed June 29, 2021); *see also Humana Inc. v. Teva Pharmaceuticals USA, Inc.*, case no. 21-cv-00072 (M.D. Fla.) (complaint January 8, 2021).

190. Teva's business practices are subject to the antitrust laws, and so it was reasonable for Plaintiffs and Class members to presume that Teva was operating in a competitive market. A reasonable person under the circumstances would not have had occasion to suspect that Teva was engaged in an overarching monopolization scheme to suppress generic competition until September 30, 2020, when the Staff Report was published.

191. Because Teva's monopolization scheme is self-concealing and was affirmatively concealed by Teva, Plaintiffs and the members of the class had no knowledge of the scheme prior to the applicable statute of limitations in relation to the filing of this complaint. As a result of Teva's fraudulent concealment, all applicable statutes of limitations affecting the claims of Plaintiffs and members of the class have been tolled.

XII. COMPLIANCE WITH NOTICE AND DEMAND REQUIREMENTS

192. In accordance with the requirements of Arizona Revised Statute § 44-1415; Hawaii Revised Statute § 480-13.3(a); Minn. Stat. § 325D.63; Nevada Revised Statute § 598A.210(3); Or. Rev. Stat. § 646.780(5)(b); Rhode Island General Laws § 6-36-21; and Utah Code § 76-10-3109, on or about March 11, 2022, Plaintiffs' counsel sent letters regarding this class-action complaint

to the Attorneys General of Arizona, Hawaii, Minnesota, Nevada, Oregon, Rhode Island, and Utah. The letters informed the Attorneys General of the existence of this complaint, identified the relevant state antitrust provisions at issue, and enclosed a copy of this complaint.

193. On or about March 11, 2022, counsel sent demand letters to the Teva Defendants regarding this class-action complaint, which satisfy the demand-letter requirements of certain consumer-protection statutes mentioned below (e.g., California and Massachusetts). The demand letters identified the claimant as Plaintiffs, in their individual and representative capacity; described the allegedly unfair or deceptive acts or practices committed by Teva (i.e., its efforts to suppress competition from generic Copaxone); described Plaintiffs' and the class's injury (increased prices for Copaxone); set forth a demand for relief (treble damages, attorneys' fees, litigation costs, and other available sanctions); and requested an offer to cure within the statutorily prescribed time.

XIII. CLAIMS FOR RELIEF

CLAIM I:
MONOPOLIZATION AND MONOPOLISTIC SCHEME UNDER ANTITRUST STATE LAWS

194. Plaintiffs incorporate by reference all the allegations above as though fully set forth herein.

195. At all relevant times, Teva possessed substantial market power (i.e., monopoly power) in the relevant market. Teva possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

196. Through its overarching anticompetitive scheme, as alleged above, Teva willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or a historic accident, and thereby injured Plaintiffs and the class.

197. Had Teva competed on the merits instead of unlawfully maintaining its monopoly in the market for glatiramer acetate, Plaintiffs and the class members would have substituted more lower-priced generic Copaxone for the higher-priced brand-name Copaxone for some or all of their Copaxone requirements, and would have paid substantially lower prices for brand-name Copaxone and generic Copaxone.

198. The goal, purpose, and effect of Teva's overarching anticompetitive scheme was to suppress generic competition for glatiramer acetate, extend its dominance in that market, and maintain Copaxone's prices at supracompetitive levels.

199. Teva's scheme substantially harmed competition in the relevant market.

200. There is and was no non-pretextual, procompetitive justification for Teva's actions that outweighs the scheme's harmful effects. Even if there were some conceivable justification that Teva could assert, the scheme is and was broader than necessary to achieve such a purpose.

201. But for Teva's illegal conduct, generic manufacturers of GA would have been able to fairly compete with Teva in a full and timely manner, and Plaintiffs and Class members, who are third-party payors, would have substituted lower-priced generic GA for some or all of their Copaxone purchases and/or paid lower prices for their branded Copaxone purchases. Plaintiffs and Class members would have purchased lower-priced GA in substantially larger quantities.

202. By engaging in the foregoing conduct, Teva intentionally, willfully, and wrongfully monopolized the relevant market in violation of the following state laws:

a. Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchase of Copaxone and generic GA in Arizona by class members and/or purchases by Arizona residents.

b. Conn. Gen. Stat. §§ 35-24, *et seq*., with respect to purchase of Copaxone and generic GA in Connecticut by class members and/or purchases by Connecticut residents.

c. D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchase of Copaxone and generic GA in the District of Columbia by class members and/or purchases by D.C. residents.

d. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchase of Copaxone and generic GA in Illinois by class members and/or purchases by Illinois residents.

e. Iowa Code §§ 553.1, *et seq.*, with respect to purchase of Copaxone and generic GA in Iowa by class members and/or purchases by Iowa residents.

f. Kan. Stat. §§ 50-101, *et seq.*, with respect to purchase of Copaxone and generic GA in Kansas by class members and/or purchases by Kansas residents.

g. Me. Rev. Stat. 10 §§ 1102, *et seq.*, with respect to purchase of Copaxone and generic GA in Maine by class members and/or purchases by Maine residents.

h. Md. Com'l Law Code Ann. §§ 11-201, *et seq.*, with respect to purchase of Copaxone and generic GA in Maryland by Plaintiff the City of Baltimore.

i. Mich. Comp. Laws §§ 445.771, *et seq.*, with respect to purchase of Copaxone and generic GA in Michigan by class members and/or purchases by Michigan residents.

j. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchase of Copaxone and generic GA in Minnesota by class members and/or purchases by Minnesota residents.

k. Miss. Code §§ 75-21-1, *et seq.*, with respect to purchase of Copaxone and generic GA in Mississippi by class members and/or purchases by Mississippi residents.

l. Neb. Code §§ 59-801, *et seq.*, with respect to purchase of Copaxone and generic GA in Nebraska by class members and/or purchases by Nebraska residents.

m. Nev. Rev. Stat. §§ 598A.010, *et seq.*, with respect to purchase of Copaxone and generic GA in Nevada by class members and/or purchases by Nevada residents

n. N.H. Rev. Stat. §§ 356:1, *et seq.*, with respect to purchase of Copaxone and generic GA in New Hampshire by class members and/or purchases by New Hampshire residents.

o. N.M. Stat. §§ 57-1-1, *et seq.*, with respect to purchase of Copaxone and generic GA in New Mexico by class members and/or purchases by New Mexico residents.

p. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchase of Copaxone and generic GA in North Carolina by class members and/or purchases by North Carolina residents.

q. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchase of Copaxone and generic GA in North Dakota by class members and/or purchases by North Dakota residents.

r. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchase of Copaxone and generic GA in Oregon by class members and/or purchases by Oregon residents.

s. P.R. Laws tit. 10 §§ 257, *et seq.*, with respect to purchase of Copaxone and generic GA in Puerto Rico by class members and/or purchases by Puerto Rico residents.

t. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchase of Copaxone and generic GA in Rhode Island by class members and/or purchases by Rhode Island residents.

u. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchase of Copaxone and generic GA in South Dakota by class members and/or purchases by South Dakota residents.

v. Utah Code Ann. §§ 76-10-3101, *et seq.* with respect to purchase of Copaxone and generic GA in Utah by class members and/or purchases by Utah residents.

w. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchase of Copaxone and generic GA in West Virginia by class members and/or purchases by West Virginia residents.

x. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchase of Copaxone and generic GA in Wisconsin by class members and/or purchases by Wisconsin residents.

203. As a direct and proximate result of Teva's monopolistic conduct, Plaintiffs and the class have suffered injury to their business and property in that they have paid more for glatiramer acetate than they would have paid in the absence of Teva's unlawful conduct. By reason of the foregoing, Plaintiffs and members of the class are entitled to seek all forms of relief available,

including damages and multiple damages, as permitted by law for Teva's violations of the foregoing statutes.

CLAIM II:
EXCLUSIVE DEALING UNDER ANTITRUST STATE LAWS

204. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

205.

206. At all relevant times, Teva possessed substantial market power (i.e., monopoly power) in the relevant market. Teva possessed the power to control prices, to prevent prices from falling in, and exclude competitors from the relevant market and to suppress generic competition.

207. Teva's market power is coupled with strong regulatory and contractual barriers to entry into the relevant market.

208. As alleged extensively above, Teva willfully maintained monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or a historic accident, and thereby injured Plaintiffs and the class.

209. Had Teva competed on the merits instead of unlawfully maintaining its monopoly in the market for glatiramer acetate, Plaintiffs and the class members would have substituted more lower-priced generic Copaxone for the higher-priced brand-name Copaxone for some or all of their Copaxone requirements, and would have paid substantially lower prices for brand-name and generic Copaxone.

210. The goal, purpose, and effect of Teva's anticompetitive conduct was to suppress generic competition for glatiramer acetate, extend its dominance in that market, and maintain Copaxone's prices at supracompetitive levels.

211. As stated more fully above, Teva knowingly, willfully, and wrongfully maintained monopoly power and harmed competition by entering into exclusionary contracts with PBMs and specialty pharmacies to exclude generic Copaxone from formularies and bar specialty pharmacies from dispensing generic Copaxone.

212. Teva's anticompetitive conduct is exclusionary conduct – the purpose and effect of which is to willfully maintain monopoly power, which harms purchasers, the competitive process, and consumers, in violation of state antitrust laws.

213. There is and was no cognizable, non-pretextual, procompetitive justification for Teva's exclusionary conduct that outweighs its harmful effects. Even if there were some conceivable justification that Teva were permitted to assert, its conduct is and was broader than necessary to achieve such a purpose.

214. But for Teva's illegal conduct, generic manufacturers of GA would have been able to fairly compete with Teva in a full and timely manner, and Plaintiffs and Class members, who are third-party payors, would have substituted lower-priced generic GA for some or all of their Copaxone purchases and/or paid lower prices for their branded Copaxone purchases. Plaintiffs and Class members would have purchased lower-priced GA in substantially larger quantities.

215. By engaging in the foregoing conduct, Teva intentionally, willfully, and wrongfully monopolized the relevant market in violation of the following state laws:

a. Ariz. Rev. Stat. §§44-1401, *et seq.*, with respect to purchase of Copaxone and generic GA in Arizona by class members and/or purchases by Arizona residents.

b. Conn. Gen. Stat. §§ 35-24, et seq. with respect to purchase of Copaxone and generic GA in Connecticut by class members and/or purchases by Connecticut residents.

c. D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchase of Copaxone and generic GA in the District of Columbia by class members and/or purchases by D.C. residents.

d. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchase of Copaxone and generic GA in Illinois by class members and/or purchases by Illinois residents.

e. Iowa Code § 553.1, *et seq.*, with respect to purchase of Copaxone and generic GA in Iowa by class members and/or purchases by Iowa residents.

f. Kan. Stat. §§ 50-101, *et seq.*, with respect to purchase of Copaxone and generic GA in Kansas by class members and/or purchases by Kansas residents.

g. Me. Rev. Stat. 10 § 1102, *et seq.*, with respect to purchase of Copaxone and generic GA in Maine by class members and/or purchases by Maine residents.

h. Md. Com'l Law Code Ann. § 11-201, *et seq.*, with respect to purchase of Copaxone and generic GA in Maryland by Plaintiff the City of Baltimore.

i. Mich. Comp. Laws §§ 445.771, *et seq.*, with respect to purchase of Copaxone and generic GA in Michigan by class members and/or purchases by Michigan residents.

j. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchase of Copaxone and generic GA in Minnesota by class members and/or purchases by Minnesota residents.

k. Miss. Code §§ 75-21-1, *et seq.*, with respect to purchase of Copaxone and generic GA in Mississippi by class members and/or purchases by Mississippi residents.

l. Neb. Code §§ 59-801, *et seq.*, with respect to purchase of Copaxone and generic GA in Nebraska by class members and/or purchases by Nebraska residents.

m. Nev. Rev. Stat. §§ 598A.010, *et seq.*, with respect to purchase of Copaxone and generic GA in Nevada by class members and/or purchases by Nevada residents

n. N.H. Rev. Stat. §§ 356:1, *et seq.*, with respect to purchase of Copaxone and generic GA in New Hampshire by class members and/or purchases by New Hampshire residents.

o. N.M. Stat. §§ 57-1-1, *et seq.*, with respect to purchase of Copaxone and generic GA in New Mexico by class members and/or purchases by New Mexico residents.

p. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchase of Copaxone and generic GA in North Carolina by class members and/or purchases by North Carolina residents.

q. N.D. Cent. Code § 51-08.1-01, *et seq.*, with respect to purchase of Copaxone and generic GA in North Dakota by class members and/or purchases by North Dakota residents.

r. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchase of Copaxone and generic GA in Oregon by class members and/or purchases by Oregon residents.

s. P.R. Laws tit. 10 § 257, *et seq.*, with respect to purchase of Copaxone and generic GA in Puerto Rico by class members and/or purchases by Puerto Rico residents.

t. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchase of Copaxone and generic GA in Rhode Island by class members and/or purchases by Rhode Island residents.

u. S.D. Codified Laws § 37-1-3.1, *et seq.*, with respect to purchase of Copaxone and generic GA in South Dakota by class members and/or purchases by South Dakota residents.

v. Utah Code Ann. §§ 76-10-3101, *et seq.* with respect to purchase of Copaxone and generic GA in Utah by class members and/or purchases by Utah residents.

w. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchase of Copaxone and generic GA in West Virginia by class members and/or purchases by West Virginia residents.

x. Wis. Stat. § 133.01, *et seq.*, with respect to purchase of Copaxone and generic GA in Wisconsin by class members and/or purchases by Wisconsin residents.

216. As a direct and proximate result of Teva's monopolistic conduct, Plaintiffs and the class have suffered injury to their business and property in that they have paid more for glatiramer acetate than they would have paid in the absence of Teva's unlawful conduct. By reason of the foregoing, Plaintiffs and members of the class are entitled to seek all forms of relief available, including damages and multiple damages, as permitted by law for Teva's violations of the foregoing.

CLAIM III:

UNFAIR METHODS OF COMPETITION, AND UNFAIR DECEPTIVE ACTS, IN VIOLATION OF STATE CONSUMER-PROTECTIONS LAWS

217. Plaintiffs incorporate by reference all previous allegations of fact.

218. Teva engaged in unfair methods of competition, unfair and unconscionable acts or practices, or deceptive acts or practices, in order to wrongfully restrain trade in the glatiramer-acetate market, and in violation of the state consumer-protection statutes identified below.

219. As noted in detail above, these practices include ; (1) entering into exclusionary agreements with PBMs, in order to block generic Copaxone's inclusion on formularies; (2) reaching exclusionary agreements with PBM-owned specialty pharmacies to dispense branded Copaxone even if a prescription was written specifically for generic Copaxone; (3) disseminating false and misleading information about generic Copaxone to healthcare providers, payors, and patients; (4) engaging in a "DAW" campaign; and (5) duping health plans with an anticompetitive consumer copay "coupon" scheme that circumvented plan members' cost-sharing obligations and helped artificially increase and protect brand Copaxone's high prices—all of which inhibited the uptake of generic Copaxone.

220. As a proximate result of Teva's unfair, unconscionable, and deceptive conduct, Plaintiffs and the class were: (1) denied the opportunity to purchase lower-priced generic Copaxone; and (2) paid higher prices for brand Copaxone than they otherwise would have but for Teva's unlawful conduct.

221. In other words, there was and is a gross disparity between the price that Plaintiffs and the class members actually paid for Copaxone and the price that they would have paid absent Teva's conduct. Much more affordable generic Copaxone would have been available, and prices for brand Copaxone would have been far lower, but for Teva's unfair, unconscionable, and

deceptive conduct. This injury is of the type the state consumer-protection statutes were designed to prevent, and (again) it directly results from Teva's unlawful conduct.

222. To the extent deception is required under any of the state laws below, but for Teva's deceptive acts, Copaxone prices would have been lower. For example, if Teva hadn't campaigned to disparage generic Copaxone, then the generic-Copaxone market would have been more robust, which—in turn—would have driven down the market price of brand Copaxone. Relatedly, Teva's deceptive conduct—such as suggesting that its brand product was superior to generic Copaxone—allowed Teva to charge a higher price for brand Copaxone than it otherwise could have (i.e., Teva's misstatements allowed the company to charge a premium for brand Copaxone). In other words, Teva's misstatements resulted in overcharges to Plaintiffs and the class, even if considered independently of the rest of Teva's unfair business practices (e.g., its exclusivity agreements with PBMs).

223. The gravity of harm from Teva's wrongful conduct significantly outweighs any conceivable utility from that conduct. Plaintiffs and the class members could not have reasonably avoided injury from Teva's wrongful conduct.

224. By engaging in such conduct, Teva violated the following consumer-protection laws:

***California*:**

225. Plaintiffs incorporate each allegation set forth in the preceding paragraphs of this complaint.

226. Section 17200 *et seq.* of the California Business and Professional Code (the "UCL") prohibits any "unlawful, unfair, or fraudulent act or practice[]."

227. Teva violated the UCL by (among other things) engaging in its scheme to suppress the availability of generic Copaxone, which is described above, and which included, among other things, exclusionary agreements with PBMs; efforts to circumvent DAW requirements; and falsely disparaging generic competition.

228. Teva violated the UCL's unlawful prong insofar as its conduct also violated federal antitrust law, as well as California's antitrust law (CA BUS & PROF § 16720).

229. Teva's conduct also constitutes unfair or unconscionable acts or practices under the UCL, regardless of whether or not that conduct violates state or federal antitrust laws.

230. Teva's conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiffs and members of the class.

231. Teva's conduct did deceive and would have deceived reasonable persons, including Plaintiffs and the class.

232. Plaintiffs and/or members of the class purchased glatiramer acetate within California during the Class Period.

233. Teva's conduct was the proximate cause of injuries to Plaintiffs and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiffs and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva's efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand

Copaxone; i.e., as a result of Teva's false statements, Plaintiffs and the class had to pay more for brand Copaxone than that product was actually worth.

234. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiffs will suffer injury in the future, as a result of Teva's conduct.

235. This claim is instituted pursuant to sections 17203 and 17204 of the California Business and Professions Code, to obtain restitution from Teva for acts that violated the UCL, as described above.

236. Plaintiffs and the class are entitled to full restitution and disgorgement of all revenues, earnings, profits, compensation, and benefits that Teva may have obtained as a result of its efforts to suppress generic Copaxone, or as a result of its efforts to mislead patients and providers regarding the relative efficacy or safety of generic Copaxone. Plaintiffs and the class are also entitled to all other appropriate relief under the UCL.

***Florida*:**

237. Plaintiffs incorporate each allegation set forth in the preceding paragraphs of this complaint.

238. The Florida Deceptive and Unfair Trade Practices Act (the "FDUTPA") prohibits "unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." FLA STAT. § 501.204(1).

239. Teva engaged in unfair methods of competition by (among other things) suppressing competition in the glatiramer-acetate market, which it did by entering into agreements with PBMs to exclude generic Copaxone from formularies; convincing specialty pharmacies to

ignore DAW prescriptions and to dispense brand Copaxone; and by engaging in a campaign to falsely disparage the relative efficacy of generic Copaxone.

240. Teva's conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiffs and members of the class.

241. Teva's conduct did deceive and would have deceived reasonable persons, including Plaintiffs and the class.

242. During the Class Period, Teva and the class purchased Copaxone in Florida.

243. Teva's conduct was the proximate cause of injuries to Plaintiffs and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiffs and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva's efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva's false statements, Plaintiffs and the class had to pay more for brand Copaxone than that product was actually worth.

244. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiffs will suffer injury in the future, as a result of Teva's conduct.

245. In light of the above, Plaintiffs and members of the class are entitled to seek all forms of relief under the FDUTPA, including injunctive relief pursuant to Florida Statute

§ 501.208, as well as a declaratory judgment, actual damages, punitive damages (to the extent available), reasonable attorneys' fees and costs. *See* FLA. STAT. § 501.211.

***Hawaii*:**

246. Plaintiffs incorporate each allegation set forth in the preceding paragraphs of this complaint.

247. Hawaii's Unfair and Deceptive Acts or Trade Practices Act prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." HAW. REV. STAT. § 480-2.

248. Hawaii's Uniform Deceptive Trade Practices Act prohibits Defendants from (among other things) "[d]isparag[ing] the goods, services, or business of another by false or misleading representation of fact." HAW. REV. STAT. § 481A-3(8); *see also id.* at (5), (7), (12).

249. Teva's anticompetitive efforts to suppress generic Copaxone, which are described above, constituted an unfair method of competition, or an unfair trade practice, under Hawaii's Unfair and Deceptive Acts or Trade Practices Act.

250. Teva's false or misleading statements regarding generic Copaxone (among other thing), which are also described above, constituted disparagement, false advertising, etc., under Hawaii's Deceptive Trade Practices Act.

251. Teva's conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiffs and members of the class.

252. During the Class Period, Plaintiffs and/or members of the class purchased Copaxone in Hawaii.

253. Teva's conduct was the proximate cause of injuries to Plaintiffs and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiffs and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva's efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva's false statements, Plaintiffs and the class had to pay more for brand Copaxone than that product was actually worth.

254. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiffs will suffer injury in the future, as a result of Teva's conduct.

255. In light of the above, Plaintiffs and members of the class are entitled to seek all available relief under Hawaii's consumer-protection laws, including actual damages, treble damages, punitive damages (to the extent available), injunctive relief, attorneys' fees, costs, etc.

***Idaho*:**

256. Plaintiffs incorporate each allegation set forth in the preceding paragraphs of this complaint.

257. The Idaho Consumer Protection Act (the "ICPA") prohibits "unfair methods of competition and unfair or deceptive acts and practices in the conduct of trade or commerce," IDAHO CODE §§ 48-601, which includes, among other things, "[d]isparaging the goods . . . of another by false or misleading representation of fact," IDAHO CODE § 48-603(8); *see also id.* at (7),

(17), (18). Idaho also prohibits "any unconscionable method, act or practice in the conduct of any trade or commerce." IDAHO CODE § 48-603C.

258. Teva's anticompetitive efforts to limit the availability of generic Copaxone, which are described above—and which included, among other things, exclusionary agreements with PBMs; efforts to circumvent DAW requirements; and falsely disparaging generic competition—constitute an unfair method of competition, or an unconscionable practice, under the ICPA. By disparaging its generic competition (among other thing), Teva also engaged in deceptive practices under the ICPA.

259. Teva intentionally engaged in the above conduct in order to inhibit generic competition. As noted above, Teva's own documents, which are detailed in the Congressional report described above, indicate that its suppression of generic Copaxone was part of an intentional, long-running, focused effort by the company to preserve branded Copaxone sales and prices, even after the loss of Teva's patent exclusivity.

260. Teva's alleged conduct—which forced sufferers of multiple sclerosis to overpay for their medication—would outrage or offend the public conscious.

261. During the Class Period, Plaintiffs and/or members of the class purchased Copaxone in Idaho.

262. Teva's conduct was the proximate cause of injuries to Plaintiffs and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiffs and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic

presence would have exerted downward price pressure on brand prices). Relatedly, Teva's efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva's false statements, Plaintiffs and the class had to pay more for brand Copaxone than that product was actually worth.

263. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiffs will suffer injury in the future, as a result of Teva's conduct.

264. In light of the above, Plaintiffs and the class are entitled to seek actual damages, along with any other form of relief that the Court deems proper under the ICPA, including actual damages, statutory damages, punitive damages, attorneys' fees, costs, injunctive relief, etc. *See* IDAHO CODE § 48-608.

***Massachusetts*:**

265. Plaintiffs incorporate each allegation set forth in the preceding paragraphs of this complaint.

266. The Massachusetts Consumer Protection Act (the "MaCPA") prohibits "unfair or deceptive act or practice." MASS. GEN. LAWS ch. 93A, § 9(2).

267. Teva's anticompetitive scheme to suppress generic Copaxone, which is described above, constituted an unfair act or practice under the MaCPA.

268. Teva's efforts to falsely denigrate generic Copaxone (among other thing), as described above, constituted a deceptive act or practice under the MaCPA.

269. Teva's conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiffs and members of the class.

270. During the Class Period, Plaintiffs and members of the class purchased glatiramer acetate within the Commonwealth of Massachusetts.

271. Teva's conduct was the proximate cause of injuries to Plaintiffs and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiffs and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva's efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva's false statements, Plaintiffs and the class had to pay more for brand Copaxone than that product was actually worth.

272. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiffs will suffer injury in the future, as a result of Teva's conduct.

273. In light of the above, Plaintiffs and the class are seeking all forms of relief under the MaCPA, including actual damages, treble damages, punitive damages (to the extent available), reasonable attorney's fees, costs, and injunctive relief. *See* MASS. GEN. LAWS ch. 93A § 9(3A).

***New York*:**

274. Plaintiffs incorporate each allegation set forth in the preceding paragraphs of this complaint.

275. New York's General Business Law prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce." N.Y. GEN. BUS. LAW § 349(a), (g); N.Y. GEN. BUS. LAW § 350 (prohibiting false advertising).

276. Teva's efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute deceptive acts or practices under the GBL.

277. Teva's conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiffs and members of the class.

278. During the Class Period, Plaintiffs and/or members of the class purchased Copaxone in New York.

279. Teva's conduct was the proximate cause of injuries to Plaintiffs and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiffs and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva's efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva's false statements, Plaintiffs and the class had to pay more for brand Copaxone than that product was actually worth.

280. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiffs will suffer injury in the future, as a result of Teva's conduct.

281. In light of the above, Plaintiffs and the class are seeking all available forms of relief under the GBL, including actual damages, treble damages, statutory damages, punitive damages (to the extent available), reasonable attorneys', costs, and injunctive relief.

***Vermont*:**

282. Plaintiffs incorporate each allegation set forth in the preceding paragraphs of this complaint.

283. Title 9 of the Vermont Statutes prohibits "[u]nfair methods of competition in commerce and unfair or deceptive acts or practices in commerce." VT. STAT. tit. 9, § 2453.

284. Teva's efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute unfair practices under § 2453. Teva also engaged in deceptive practices under the statute by (among other thing) falsely denigrating its generic competition.

285. Teva's conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiffs and members of the class.

286. During the Class Period, Plaintiffs and/or members of the class purchased Copaxone in Vermont.

287. Teva's conduct was the proximate cause of injuries to Plaintiffs and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the

merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiffs and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva's efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva's false statements, Plaintiffs and the class had to pay more for brand Copaxone than that product was actually worth.

288. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiffs will suffer injury in the future, as a result of Teva's conduct.

289. In light of the above, Plaintiffs and the class are seeking all available forms of relief under Vermont's consumer-protection statute, including actual damages, punitive damages (to the extent available), attorneys' fees, costs, and injunctive relief.

CLAIM IV:
VIOLATION OF SHERMAN ACT, 15 U.S.C. § 2
DECLARATORY AND INJUNCTIVE RELIEF

290. Plaintiffs incorporate by reference all previous allegations of fact as though fully set forth herein.

291. As set forth in the Counts above, Defendants have violated Section 2 of the Sherman Act, 15 U.S.C. § 2.

292. Plaintiffs request that the Court grant injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S. C. § 26 as may be necessary and appropriate to restore competition in the market for glatiramer acetate.

XIV. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on behalf of themselves and the class of all others similarly situated, respectfully request judgment against the Defendants as follows:

293. The Court determine that this action may be maintained as a class action under Rule 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure, appoint Plaintiffs as class representatives and their counsel of record as class counsel, and direct that notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Civil Procedure, be given to the class, once certified;

294. The unlawful conduct alleged herein be adjudged and decreed in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2 and the listed state antitrust laws, unfair competition laws, state consumer protection laws, and common law;

295. Plaintiffs and the class recover damages, to the maximum extent allowed under the applicable laws, and that a joint and several judgment in favor of Plaintiffs and members of the class be entered in an amount to be trebled to the extent such laws permit;

296. The Court grant permanent injunctive relief: a. enjoining the Defendants from continuing their illegal conduct; b. enjoining the Defendants from engaging in future anticompetitive conduct with the purpose or effect of delaying the entry of generic glatiramer acetate or other generic drugs;

297. The Court Grant Plaintiffs and the proposed class equitable relief in the nature of disgorgement and restitution;

298. Plaintiffs and the members of the proposed class be awarded pre- and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of this complaint;

299. Plaintiffs and members of the proposed class recover their costs of suit, including reasonable attorneys' fees, as provided by law; and

300. Plaintiffs and members of the proposed class be awarded such other and further relief as the case may require and the Court may deem just and proper.

XV. JURY DEMAND

301. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs, on behalf of themselves and the proposed class, demand a trial by jury of all issues so triable.

Dated: April 29, 2022

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